Suomen rokotetutkimus
Finnish Vaccine Research

STUDIES CONDUCTED BEFORE YEAR 2017

A phase I/II, randomized, observer-blind, controlled multi-country study to assess the safety, reactogenicity and immunogenicity of a single intramuscular dose of GSK Biologicals' investigational RSV vaccine (GSK3003891A) in healthy pregnant women aged 18 to 40 years and infants born to vaccinated mothers.
Start: November 2016
GSK RSV F-004
EudraCT: 2016-002733-30

An open-label phase III clinical trial to study the immunogenicity and tolerability of GARDASIL®9 (A Multivalent Human Papillomavirus [HPV] L1 Virus-Like Particle [VLP] Vaccine) in adult women (27- to 45-year-olds) compared to young adult women (16 to 26 year olds).
Start: July 2016
Merck Sharp & Dohme Corp./MSD Finland Oy, HPV V503-004
EudraCT NUMBER: 2015-005093-38

Immunogenicity and safety of an investigational quadrivalent meningococcal conjugate vaccine in toddlers 12 to 23 months of age.
Start: november 2016
Sanofi Pasteur MET-51
EudraCT: 2016-000749-30
Vaccine Research Clinics: Etelä-Helsinki, Itä-Helsinki, Espoo, Järvenpää, Tampere, Pori, Turku, Seinäjoki, Kokkola, Oulu.

Evaluation of Immunogenicity and Safety of a Booster Dose of Infanrix Hexa™ in Healthy Infants Born to Mothers Vaccinated With Boostrix™ During Pregnancy or Immediately Post-delivery.
GSK DTPA (Boostrix)-048
EudraCT: 2014-001120-30

A Phase IV, observer-blind, randomised, cross-over, placebo-controlled, multicentre study to assess the immunogenicity and safety of a single dose of Boostrix™ in pregnant women.
Star: 2014
GSK DTPA (BOOSTRIX)-047
EudraCT: 2014-001119-38

A phase 2b, open-label, multi-center study assessing the Immunological persistence of antibodies at approximately 2 years after the last meningococcal vaccination in study V102_15 and the response to a booster dose of GSK Men ABCWY or meningococcal serogroup B vaccines, in healthy adolescents.
Start: November 2016
GSK V102_15E1
EudraCT: 2016-002230-69

A phase IIIA, randomized, partially-blind, multi-center study to evaluate the clinical consistency of three production lots of the Porcine circovirus (PCV)-free liquid formulation of GlaxoSmithKline (GSK) Biologicals' oral live attenuated human rotavirus (HRV) vaccine and to evaluate the PCV-free liquid formulation of GSK Biologicals' HRV vaccine as compared to the currently licensed lyophilized formulation of the HRV vaccine in terms of immunogenicity, reactogenicity and safety when administered as a two-dose vaccination in healthy infants starting at age 6-12 weeks.
Start: November 2016
GSK: ROTA_081
EudraCT: 2016-000598-19

A Phase 2, randomized, controlled, observer-blinded study, conducted to describe the immunogenicity, safety and tolerability of A Neisseria Meningitidis serogroup B bivalent recombinant lipoprotein 2086 Vaccine (Bivalent Rlp2086) when administered to healthy toddlers aged 12 to <18 months or 18 to <24 months.
Start: August 2015
Pfizer B1971035
EudraCT: 2011-004400-38

Long-term persistance of hepatitis B and pertussis antibody responses in healthy 4-to 5-year old children previously vaccinated with a 2-dose or 3-dose primary series and booster schedule with Vaxelis or Infanrix hexa.
Sanofi Pasteur PRI03C
EudraCT: 2016-000274-37
Vaccine Research Clinics: Etelä-Helsinki, Itä-Helsinki, Espoo, Järvenpää, Tampere, Pori, Turku, Seinäjoki, Kokkola, Oulu.

A Phase IIIB, non-randomized, open-label, multi-country, multi-centric cross-vaccination study to evaluate the safety of GSK Biologicals' Herpes Zoster subunit (HZ/su) vaccine (GSK 1437173A) when administered intramuscularly on a two-dose schedule to subjects who previously received placebo in ZOSTER-006 or ZOSTER-022 studies.
Start: November 2015
GSK Zoster 056
EudraCT: 2015-00965-30

A phase 3 study to assess the persistence of hSBA response up to 48 motnhs after completion of a primary series of bivalent rLP2086, and the safety, toleralibility, and immunogenicity of a booster dose of bivalent rLP2086.
Start: September 2012
Pfizer B1971033
EudraCT: 2011-005697-313

A phase III, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of **a human monoclonal antibody, REGN2222**, for the prevention of medically attended RSV infection in preterm infants.
Start: August 2015
Regeneron R2222-RSV-1332
EudraCT: 2015-001714-96

A Phase II, Randomized, Double-Blind, Dosage and Adjuvant Justification, safety and Immunogenicity Trial of Intramuscular Norovirus GI.1/GII.4 Bivalent Virus-Like Particle Vaccine combined with Aluminum Hydroxide, with and without Monophosphoryl Lipid A Adjuvant on Children, Todlers, and Infants.
Start: June 2015
Takeda: NOR-202
EudraCT: 2014-000778-20

A phase III, open, multi-centre, controlled study to evaluate the long-term antibody persistence at 2, 3, 4, 5 and 6 years after a booster dose of GlaxoSmithKline (GSK) Biologicals' meningococcal serogroup A, C, W-135, Y- tetanus toxoid conjugate vaccine (MenACWY-TT) versus one dose of Meningitec™ administered in healthy 5 year old children in the study MENACWY-TT-048 EXT: 039 Y2, 3, 4, 5 (112036), who were primed with the same vaccine in the study MENACWY-TT-039 (109670) at 12-24 months of age.
Start: April 2015
GSK: Men-ACWY-TT-102 EXT: 048 Y2, 3, 4, 5, 6)
EudraCT: 2012-005816-25

A Phase IIIb open. multi-center study to evaluate the long-term antibody persistence at 6, 7, 8, 9, and 10 years afetr the administration of one dose of GlaxoSmithKline (GSK) Biologicals' meningococcal conjugate vaccine MenACWY-TT versus one dose of Meningetec™ vaccine or one dose of GSK's menongococcal polysaccharide vaccine Mencevax ACWY, and to evaluate the safety and immunogenicity of a booster dose of MenACWY-TT vaccine administered 10 uears after primary vaccination of 1-10 years old subjects with *MenACWY-TT, Meningetec or Mencevax ACWY.*
Start: April 2015
GSK: Men ACWY-TT-100 EXT: 027 Y6, 7, 8, 9, 10)
EudraCT: 2013-001549-15

A Phase III, Randomized, Observer Blind, Multicenter Study to Evaluate the Safety and Immunogenicity of Repeated Exposure to an Adjuvanted Quadrivalent Subunit Influenza Virus Vaccine (aQIV), Administered to Subjects Previously Vaccinated in Trial V118_05.
Star: October 2014
Novartis: V118_05E1
EudraCT: 2014-002599-95

A phase III open-label randomised study to evaluate the immunogenicity and safety of the concomitant administration of a new
Hexavalent DTaP-IPV-HepB-PRP-T combined vaccine (Hexavalent vaccine) given at 2, 3, and 4 months of age with a meningococcal
serogroup C conjugate (MenC) vaccine given at 2 and 4 months of age.
Booster part of HXM01C clinical study:
Concomitant administration of a new hexavalent vaccine with a meningococcal conjugate vaccine in healthy infants during primary series immunisation followed by booster vaccination. (MRR vaccine provided).
Start: April 2013, booster part April 2014
Sanofi Pasteur HXM01C
EudraCT: 2012-005547-24
Vaccine Research Clinics: Etelä- ja Itä-Helsinki, Espoo, Oulu, Tampere, Turku, Järvenpää, Itä-Vantaa, Seinäjoki, Kokkola ja Pori.

A prospective, epidemiological, interventional, multi-country based, cohort study to assess the disease burden of respiratory syncytial virus (RSV) associated lower respiratory tract infections (LRTIs) in newborns, from birth up to 2 years of age.
Start: December 2013
GSK: 200150 (EPI-RSV-005 BOD)

A Phase III, Stratified, Randomized, Observer Blind, Controlled, Multicenter Clinical Study to Evaluate the Safety, Immunogenicity and Efficacy of an Adjuvanted Quadrivalent Subunit Influenza Virus Vaccine Compared to Non-Adjuvanted Comparator Influenza Vaccine in Children ≥6 to < 72 Months of Age.
Start: October 2013
Novartis: V118_05
EudraCT: 2012-000218-12

Efficacy, Immunogenicity, and Safety Study of Clostridium difficile Toxoid Vaccine in Subjects at Risk for C. difficile Infection. To assess the efficacy of the C. difficile vaccine in preventing the onset of symptomatic primary C. difficile infection (CDI) confirmed by polymerase chain reaction (PCR) in adult subjects aged ≥ 50 years who are at risk for CDI and have received at least 1 injection.
Start: October 2013

Sanofi Pasteur: H-030-014
EudraCT: 2013-000775-32

Phase III, randomized, double-blind, active-controlled, multi-center trial to assess safety and immunogenicity of the quadrivalent influenza vaccine administered via the intramuscular route in 1225 child subjects aged 3 to 8 years.
Start: September 2013
Sanofi Pasteur: GQM02
EudraCT: 2011-005374-33

A double-blind, randomized, controlled multicenter study to evaluate the safety, tolerability and immunogenicity of a new formulation of RotaTeq™ rotavirusvaccine given in healthy infants aged 6-12 weeks.
Start: June 2013
Merck V260-035
EudraCT: 2012-001611-23

A Phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck's MMR vaccine (M-M-R®II), as a first dose, both co-administered with Varivax® and Havrix® to healthy children 12 to 15 months of age.
Start: November 2012
GSK Biological MMR-160
EurdaCT: 2011-004891-12

A phase III randomized, double-blind, active-comparator controlled clinical trial to study the safety, tolerability, and immunogenicity of PR51 hexavalent vaccine in healthy infants when given at 2, 4 and 11 to 12 months
Start: 1 Mar 2012
Merck Sharp&Dohme corp, V419-008
EurdaCT: 2010-021491-28

A multicenter, double-blind study of the safety, tolerability, and immunogenicity of pneumococcal conjugate vaccine (V114) compared to Prevnar™13 in healthy infants. Prot. V114-003.
Start: November 2010
Marck V114-003

Phase III randomized, double-blind study evaluating the immunogenicity and tolerability of the new 9-valent HPV papillomavirus vaccine (V503) compared to the Gardasil® vaccine already on the market for children and young people aged 9-15 years.
Start: Feb 2011

Sanofi Pasteur MSD GDS01C, V503-009
EudraCT:2010-023393-39

Phase III double-blind, multi-centre study evaluating the efficacy, tolerability and manufacturing consistency of a new 9-valent HPV papillomavirus vaccine (V503) in preadolescents and adolescents (aged 9-15 years) with comparison to young women (aged 16-26 years).
Start: Nov 2009
MSD 503-002
EudraCT: 2010-023393-39

The study evaluates the immunogenicity and safety of the 2010/2011 seasonal influenza vaccine (Fluarix™) in young people aged 10 to 17, who have already received one dose of GSK Pandemrix™ vaccine. There are two study groups and subjects are allocated by computer to one of these. Subjects receive either one dose of seasonal influenza vaccine or two doses of control vaccine, which is GSK hepatitis A vaccine Havrix™.
Start: 4.10.2010
GSK FLU D-PAN H1N1-AS03-044 (114452)

A phase III ramdomized, observer-blind, placebo-control multi-centre study to assess the efficacy, safety and immunogenicity of Herpes zoster vaccine (GSK1437173A), when administered intramuscularly on a 0, 2 -month schedule on adults aged 50-69 years.
Start: September 2010
GSK 113090-006
EudraCT: 2008-000367-42

A phase III randomized, observer-blinded, placebo-control multi-centre trial to assess the profylactic efficacy, safety and immunogenicity of Herpes zoster vaccine (GSK1437173A) on adults aged over 70 years, when administered on a 0, 2 -month schedule in adults aged 70 years and older.
Start: September 2010
GSK 113077-022
EudraCT: 2009-015791-94

Phase III doubleblind cluster-randomized controlled study evaluating the impact on nasopharyngeal carriagem immunogenicity and safety of GSK Biologicals' 10-valent pneumococcal and non-typeable Haemophilus influenzae protein D conjugate vaccine in children starting vaccination below 18 months of age.
Start: February 2009
GlaxoSmith Kline Biologicals 112595 (10PN-PD-DID-053)
EudraCT: 2008-006551-51

ROTAVIRUS DIARRHOEA FOLLOW-UP STUDY AFTER INITIATION OF GENERAL ROTAVIRUS (ROTATEQ) VACCINATION ON FINNISH CHILD HEALTH CLINICS
An epidemiological study for children under the age of 16 years hospitalized for gastroenteritis. The purpose is to ascertain whether use of rotavirus vaccine reduces children's contracting rotavirus and if the hospitalizations due to this diminish. Rotavirus vaccine was included in the finnish national vaccination programme in September 2009.
Start: December 2009

Sanofi Pasteur MSD RTQ01E
EudraCT:

Phase I/II study to assess the safety and immunogenicity of ver cell-derived whole virus influenza vaccine in healthy infants, children and adolescents aged 6 months to 17 years.
Start: Dec 2009 – Aug 2012

Baxter 810706
EudraCT: 2009-013105-34

A phase I/IIa, randomized, double-blind, placebo-controlled, dose-escalation study to evaluate the safety, tolerability, immunogenicity and vaccine-like viral shedding of MEDI-534, a live, attenuated intranasal vaccine against respiratory syncytial virus (RSV) and parainfluenza virus type 3 (PIV3), in healthy 6 to < 24 month-old children and in 2 month-old infants.
Study clinics: Tampere, Lahti, Kokkola, Helsinki South, Helsinki East, Järvenpää, Kuopio, Oulu, Pori, Turku
Starting date in April 2009

MedImmune MI-CP178
EudraCT: 2008-002651-24

A phase III, randomized, double-blind and active-controlled study in children and adolescents aged 3-17 years to assess the safety and immunogenicity of Abbot's candidate quadrivalent influenza vaccine and it's non-inferiority versus trivalent influenza vaccine.
Start: August 2016

Abbot INFQ3002
EudraCT: 2015-005482-23

A phase III, randomized, observer blind, multicenter study to evaluate the safety and immunogenicity of repeated exposure to either the same or alternate type of vaccine, adjuvanted or non-adjuvanted quadrivalent subunit influenza virus vaccine (aQIV or QIV), administered to subjects previously vaccinated in trial V118_05.

Start: January 2016
Novartis V118_05E3

A Phase II, randomized, controlled, observer-blinded study to describe the immunogenicity, safety and tolerability of *neisseria meningitidis* serogroup B bivalent recombinant lipoprotein 2086 vaccine (bivalent rLP 2086) in healthy subjects aged ≥24 months to < years.
Start: August 2015
Pfizer B1971017
EudraCT: 2014-000933-21

A Phase II, randomized, open-label, active-controlled study to describe the safety and immunogenicity of MenACYW conjugate vaccine compared to NIMENRIX® in toddlers 12 to 23 months of age.
Start: March 2015
Sanofi Pasteur: MET-54 (Men ACYW Conjugate Vaccine)
EudraCT: 2014-004367-20

A Phase 2b, Randomized, Controlled, Observer-Blind, Multi-Center Study Assessing the Immunogenicity and Safety of Novartis Meningococcal ABCWY Vaccine Administered at Different Schedules Compared to Novartis Meningococcal group B vaccine, in Healthy Adolescents**.**
Start: August 2014
Novartis: V102_15
EudaCT: 2014-02212457

A Phase III, Stratified, Randomized, Observer Blind, Controlled, Multicenter Clinical Study to Evaluate the Safety, Immunogenicity and Efficacy of an Adjuvanted Quadrivalent Subunit Influenza Virus Vaccine Compared to Non-Adjuvanted Comparator Influenza Vaccine in Children ≥6 to < 72 Months of Age.
Start: October 2014
Novartis: V118_05
EudraCT: 2012-000218-12

A phase IIIA randomized, observer-blind, controlled, multinationally study to evaluate the safety and immunogenicity of GSK Biologials' MMR vacine (209762 Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M-M-R II® or VaxPro®), as a first dose, both co-administered with Varivax®, Havrix® (all subjects) and Prevenar 13® (US subset) in healthy children 12 to 15 months of age.
Start: February 2015
GSK: MMR-162 (115650)
EudraCT: 2011-006161-18

Phase III, randomized, blind-observer, active-controlled, multi-center trial to study immunogenicity and safety of a hexavalent DTaP-IPV-Hep B-PRP-T combined vaccine or Infanrix hexa™concomitantly administered with 13-valent pneumococcal conjugate vaccine (PCV13) at 3, 5, 11 to 12 months of age in healthy infants in Europe.
Start: October 2012
Sanofi Pasteur A3L38
EudraCT: 2012-001054-26

A Phase IIIA, randomized, observer-blind, controlled, multinational study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) at an end of shelf-life potency compared to Merck's MMR-II vaccine (M-M-R®II). Both are co-administered with Varivax® and Havrix®, and given on a two-dose schedule to healthy children in their second year of life.
Start: November 2012
GSK Biological MMR-161
EurdaCT: 2011-004905-26

Phase II, randomized, placebo-controlled single-blind trial to assess the safety, tolerability and immunogenicity of Repevax® and rLP2086 vaccines when administered concomitantly in healthy subjects aged 11-19 years.
Start: May 2011
Pfizer B1971010
EudraCT: 2010-022449-38

Phase II randomized, placebo-controlled, single-blind trial to assess the safety, tolerability and immunogenicity of rLP2086 vaccine when administered in either 2- or 3-dose regimens in healthy aged 11-19 years.
Start: April 2011
Pfizer B1971012
EudraCT: 2009-014493-18

Phase III randomized, double-blind, active comparator controlled clinical trial to study the safety, tolerability and immunogenicity of V419 in healthy infants when administered at age 2, 3, 4 and 12 months.
Start: May 2011
Merck:V419-007 02
EudraCT: 2010-021490-37

A phase II, double-blind, multicent re study to evaluate the safety and immunogenicity of a booster dose of new formulations of GSK combinined DTPa-HBV-IPV/Hib vaccine in healthy toddlers, previously primed with three doses of the same vaccine in study (DTPa-HBV-IPV-124 PRI).
Start: 14.10.2011

GSK 114843 DTPa-HBV-IPV-125 BST:124
EudraCT:2011-000876-33

A phase III, open-label, multi-center, extension study of V72P13E1 to assess antibody persistence at one year after a fourth dose boost or two catch-up doses of Novartis meningococcal B recombinant vaccine administered starting at 12 months of age and to evaluate the response to a third dose boost or two catch-up doses starting at 24 months of age.
Study clinics: Espoo, Helsinki South, Helsinki East, Vantaa East, Vantaa West, Järvenpää, Kuopio, Lahti, Oulu, Pori, Tampere, Turku, Kotka, Seinäjoki, Kokkola
Starting date in June 2010
Novartis Vaccines V72P13E2
EudraCT: 2009-018101-52

A phase III open-label clinical trial to study the immunogenicity and tolerability of V503, a multivalent human papillomavirus (HPV) L1 virus-like particle (VLP) vaccine, given concomitantly with Repevax in preadolescents and adolescents (11 to 15 year olds).
Study clinics: Lahti, Vantaa West, Helsinki East, Järvenpää, Kotka, Pori, Kuopio
Starting date in May 2010
Merck V503-007
EudraCT: 2009-016218-26

Safety and Immunogenicity of an Intramuscular A/H5N1 Inactivated, Split Virion Pandemic Influenza Vaccine in European Children.
2009-2010
SanofiPasteur, GPA 12

A phase III, open label, multi-center, extension study to evaluate the safety, tolerability and immunogenicity of Novartis meningococcal B recombinant vaccine when administered as a booster at 12 months of age or as a two-dose catch-up to healthy toddlers who participated in study V72P13.
Study clinics: Tampere, Turku, Pori, Espoo, Lahti, Vantaa East, Vantaa West, Oulu, Helsinki South, Helsinki East, Järvenpää, Kotka, Seinäjoki, Kuopio, Kokkola
Starting date in April 2009
Novartis Vaccines V72P13E1
EudraCT: 2008-006301-17

A multicenter, double-blind study of the safety, tolerability, and immunogenicity of pnemococcal conjugate vaccine (V114) compared to Prevnar in healthy adults and toddlers.
Study clinics: Vantaa West, Helsinki East, Järvenpää
Starting date in December 2009

Merck V114-001
EudraCT: 2009-015103-58

A phase I/II study to assess the safety and immunogenicity of a vero cell-derived whole virus H5N1 influenza vaccine in healthy infants, children and adolescents aged 6 months to 17 years.
Study clinics: Tampere, Espoo, Helsinki South, Vantaa East, Oulu, Turku, Seinäjoki, Kokkola
Starting date in November 2009

Baxter 810706
EudraCT: 2009-013105-34

Immunogenicity and safety of multiple formulations of an intramuscular inactivated, split virion swine-origin A/H1N1 influenza vaccine with and without adjuvant in healthy European subjects aged 6 to 35 months.
Study clinics: Tampere, Turku, Pori, Espoo, Lahti, Vantaa East, Vantaa West, Oulu, Helsinki South, Helsinki East, Järvenpää, Kotka, Seinäjoki, Kuopio, Kokkola
Starting date in September 2009

Sanofi Pasteur GPF09
EudraCT: 2009-013858-32

Immunogenicity and safety of multiple formulations of an intramuscular inactivated, split virion swine-origin A/H1N1 influenza vaccine with and without adjuvant in healthy European subjects aged 3 to 17 years.
Study clinics: Tampere, Turku, Pori, Espoo, Lahti, Vantaa East, Vantaa West, Oulu, Helsinki South, Helsinki East, Järvenpää, Kotka, Seinäjoki, Kuopio, Kokkola
Starting date in August 2009

Sanofi Pasteur GPF08
EudraCT: 2009-013346-83

An open-label phase I/II study to assess the immunogenicity and safety of a single prime-boost vaccination schedule with a Vero cell-derived whole virus H5N1 influenza vaccine in healthy volunteers aged 18 to 59 years.
Study clinics: Espoo, Helsinki South
Starting date in February 2009

Baxter 810802
EudraCT: 2008-005133-30

A phase III double-blind, cluster-randomized, controlled study to evaluate the impact on nasopharyngeal carriage, immunogenicity and safety of GSK Biologicals' 10-valent pneumococcal and non-typeable Haemophilus influenzae protein D conjugate vaccine in children starting vaccination below 18 months of age.
Study clinics: Tampere, Turku, Pori, Espoo, Lahti, Vantaa East, Vantaa West, Oulu, Helsinki South, Helsinki East, Järvenpää, Kotka, Seinäjoki, Kuopio, Kokkola

Starting date in February 2009
GlaxoSmithKline Biologicals 112595 (10PN-PD-DIT-053)
EudraCT: 2008-006551-51

A Phase Ib, Randomized, Observer-blind, Multicenter, Factorial-Design Study to Evaluate the Safety, Tolerability and Immunogenicity of Two injections of Trivalent Inactivated Influenza Vaccine with or without One of three Different Doses of Adjuvant in Healthy Children, Aged <36 Months.
2008-2009
Novartis, V104P2

A Phase III, Randomized, Controlled, Observer-Blind, Multicenter Study to Evaluate the Safety, Tolerability and Immunogenicity of Two Doses of a Monovalent A/H5N1 Influenza Vaccine Adjuvanted with MF59 (FLUAD-H5N1), in Adult and Elderly Subjects.
2008-2009
Novartis V87P13

An open-label phase III study to assess the safety and immunogenicity of a Vero cell-derived whole virus H5N1 influenza vaccine in an adult and elderly population as well as in specified risk groups.
Study clinics: Espoo, Helsinki South, Vantaa East, Tampere, Turku
Starting date in October 2008
Baxter 810705
EudraCT: 2008-000558-11

A phase III, randomized, observer-blind, controlled, multi-center clinical study to evaluate the efficacy, safety and immunogenicity of one and two intramuscular doses of FLUAD® versus control vaccines in healthy subjects aged 6 to <72 months.
Study clinics: Tampere, Turku, Pori, Lahti, Oulu, Järvenpää, Vantaa East, Vantaa West, Helsinki East, Helsinki South, Espoo, Kotka, Kuopio, Kokkola, Seinäjoki
Starting date in October 2008
Novartis Vaccines V70P5
EudraCT: 2007-003786-41

A phase III, partially blinded, randomized, multi-center, controlled study to evaluate immunogenicity, safety and lot to lot consistency of Novartis meningococcal B recombinant vaccine when administered with routine infant vaccinations to healthy infants.
Study clinics: Tampere, Turku, Oulu, Kuopio, Pori, Lahti, Kotka, Seinäjoki, Kokkola, Helsinki East, Helsinki South, Espoo, Vantaa West, Vantaa East, Järvenpää
Starting date in June 2008
Novartis Vaccines V72P13
EudraCT: 2007-007781-38

A phase I randomized placebo-controlled, double-blind study to evaluate safety and immunogenicity of AERAS-404 when administered as a single IC31 adjuvant amount with different AERAS-404 (HyVac4) antigen amounts in HIV-negative BCG-vaccinated adults without evidence of tuberculosis infection.
Study clinic: Tampere
Starting date in May 2008
Aeras C-006-404
EudraCT: 2007-006333-14

Immunogenicity and reactogenicity of GSK Bio's DTPa-HBV-IPV/Hib vaccine when given as a booster dose. Phase II.
Study clinics: Vantaa East, Järvenpää, Turku, Pori, Tampere, Oulu
Starting date in February 2008
GlaxoSmithKline Biologicals 111344
EudraCT: 2007-005343-16

An open-label, Phase III, randomised, comparative, multi-centre study of the immunogenicity and safety of a 1-dose regimen and different 2-dose regimens of a Zoster vaccine (Live), ZOSTAVAX®, in subjects ≥ 70 years of age.
Study clinics: Tampere, Vantaa East, Vantaa West, Helsinki East, Järvenpää, Kotka
Starting date in January 2008
Sanofi Pasteur X06-Z-305
EudraCT: 2007-000744-28

A Phase III, open, randomized, controlled primary vaccination study to demonstrate the immunogenicity and safety of GlaxoSmithKline (GSK) Biologicals' meningococcal serogroup ACWY conjugate (MenACWY-TT) vaccine and its non-inferiority compared to Meningitec™ and to demonstrate the non-inferiority of the co-administartion of MenACWY-TT with Priorix-Tetra™ compared to the administration of each of the two vaccines given separately, in healthy 12 through 23-month-old children.
2007-2008
GSK, MenACWY-TT-039

A phase IIb, open, randomized, controlled primary vaccination study to evaluate the non-inferiority and the persistence of the immune response of GSK Biologicals´ meningococcal serogroup ACWY conjugate vaccine given intramuscularly versus Meningitec or Mencevax ACWY to healthy subjects aged 1 through 10 years of age.
GlaxoSmithKline Biologicals 108658 **(MenACWY-TT-027)**
EudraCT: 2006-004236-70

A phase III, open, multi-centre, controlled study to evaluate the long-term antibody persistence at 2 years, 3 years and 4 years after a single dose of GlaxoSmithKline (GSK) Biologicals' meningococcal serogroup A, C, W-135, Y – tetanus toxoid conjugate

(MenACWY-TT) vaccine versus one dose of Meningitec administered in healthy 12 through 23 month-old children who were primed in study MenACWY-TT-039 (109670) and to evaluate the immunogenicity and safety of a booster dose of the same meningococcal conjugate vaccine as given in the primary study, 4 years after priming.
Study clinics: Tampere, Turku, Pori, Espoo, Lahti, Vantaa East, Vantaa West, Oulu, Helsinki South, Helsinki East, Järvenpää, Kotka, Seinäjoki, Kuopio
Starting date in August 2009
GlaxoSmithKline Biologicals 112036 (MenACWY-TT-048)
EudraCT: 2008-003824-51

A phase II, observer-blind, parallel groups, single center, extension study to evaluate the immunogenicity and safety following a single intramuscular dose of FLUAD® or Vaxigrip® influenza vaccines in healthy children who received either one or other vaccine in previous V70P2 study.
Study clinics: Tampere, Turku, Pori, Lahti, Espoo, Vantaa, Järvenpää, Oulu
Starting date in November 2007
Novartis V70P2E1
EudraCT: 2007-003339-22

A combined phase II/III, observer-blind, randomized, multi-center study to evaluate safety, tolerability and immunogenicity of trivalent subunit influenza vaccines, produced either in mammalian cell culture or in embryonated hen eggs (Fluvirin®), in healthy children and adolescents aged 3 to 17 years.
Study clinics: Tampere, Turku, Pori, Espoo, Lahti, Vantaa East, Vantaa West, Oulu, Helsinki South, Helsinki East, Järvenpää, Kotka
Starting date in November 2007
Novartis Vaccines V58P12
EudraCT: 2007-001534-13

An open-label, phase IIIb, randomised, comparative, multi-centre study of the immunogenicity and safety of a 2-dose regimen of ProQuad® manufactured with rHA administered to healthy children from 9 months of age.
Study clinics: Tampere, Turku, Pori, Espoo, Lahti, Vantaa East, Vantaa West, Oulu, Helsinki South, Helsinki East, Järvenpää, Kotka, Seinäjoki, Kuopio, Kokkola
Starting date in November 2007
Sanofi Pasteur MSD MRV02C
EudraCT: 2007-002468-88

A phase III clinical trial to evaluate the efficacy, immunogenicity, safety and tolerability of Zostavax in subjects 50 to 59 years of age. Protocol V211-022.
Study clinics: Helsinki South, Helsinki East, Vantaa East, Vantaa West, Espoo, Järvenpää, Lahti, Turku, Pori, Tampere, Kotka, Seinäjoki, Kokkola, Kuopio, Oulu
Starting date in November 2007

Merck V211, Protocol 022
EudraCT: 2007-004020-20

A phase III, randomized, observer-blind, placebo-controlled, multicenter study to assess clinical efficacy of a cell-derived subunit influenza vaccine and an egg-derived subunit influenza vaccine in the 2007-2008 influenza season in healthy adult subjects.
Study clinics: Espoo, Helsinki South, Helsinki East, Vantaa East, Vantaa West, Järvenpää, Kokkola, Kotka, Kuopio, Lahti, Oulu, Pori, Seinäjoki, Tampere, Turku
Starting date in October 2007
Novartis Vaccines V58P13
EudraCT: 2007-002871-15

A phase II, randomized, controlled, observer-blind, single-center study to evaluate the immunogenicity, safety and tolerability of two doses of FLUAD-H5N1 influenza vaccine in subjects aged 6 months to 17 years.
Study clinics: Tampere, Turku, Pori, Espoo, Lahti, Vantaa East, Vantaa West, Oulu, Helsinki South, Helsinki East, Järvenpää, Kotka
Starting date in September 2007
Novartis Vaccines V87P6
EudraCT: 2007-002480-27

Randomized, phase I, observer-blind, placebo-controlled study to assess the immunogenicity and safety of two adjuvant formulations of an egg-derived pandemic surface antigen influenza vaccine in healthy adults aged ≥ 18 years and ≥ 49 years.
Study clinics: Turku, Helsinki South, Helsinki East, Espoo, Vantaa East, Vantaa West.
Starting date in September 2007
Solvay Pharmaceuticals S205.1.001
EudraCT: 2007-000876-17

A phase III open, randomized, controlled primary vaccination study to demonstrate the immunogenicity and safety of GlaxoSmithKline (GSK) Biologicals' meningococcal serogroup ACWY conjugate (MenACWY-TT) vaccine and its non-inferiority compared to Meningitec and demonstrate the non-inferiority of the coadministration of MenACWY-TT with Priorix-Tetra compared to the administration of each of the two vaccines given separately, in healthy 12 through 23-month-old children.
Study clinics: Tampere, Turku, Pori, Espoo, Lahti, Vantaa East, Vantaa West, Oulu, Helsinki South, Helsinki East, Seinäjoki, Järvenpää, Kotka, Kuopio
Starting date in May 2007
GlaxoSmithKline Biologicals 109670
EudraCT: 2006-006580-23

A study in healthy infants of the safety, tolerability, and immunogenicity of haemophilus influenzae, type b / hepatitis B vaccine manufactured with a modified process. Phase III.

Study clinics: Tampere, Turku, Pori, Lahti, Oulu, Järvenpää, Vantaa East, Vantaa West, Helsinki South, Espoo
Starting date in February 2007
Merck V121, Protocol 019-00
EudraCT: 2006-003648-46

An open-label, phase IIIb, randomised, comparative, multi-centre study of the immunogenicity and safety of the concomitant use of a live pentavalent rotavirus vaccine (RotaTeq®) and a meningococcal group C conjugate (MCC) vaccine in healthy infants.
Study clinics: Tampere, Pori, Turku, Järvenpää, Vantaa East, Vantaa West, Oulu, Espoo, Helsinki South
Starting date in January 2007
Sanofi Pasteur MSD S06-ROT-304
EudraCT: 2006-0054-4511

A Phase III, double-blind, randomized, placebo-controlled, multi-country and multi-center study to assess the efficacy, safety and immunogenicity of two doses of GSK Biologicals' oral live attenuated human rotavirus (HRV) vaccine in healthy infants.
GSK / Smerud, Protocol 023
December 2003 – November 2004, 2067 children
Vaccine Research Clinics: Tampere, Espoo/Tapiola, Espoon Keskus, Espoonlahti, Lahti, Pori, Turku, Jyväskylä, Vantaa West, Vantaa East, Helsinki North, Helsinki South, Helsinki East, Oulu, Kokkola, Pori, Rauma, Vaasa, Seinäjoki, Kuopio, Kotka, Järvenpää, Riihimäki, Hyvinkää, Porvoo, Lappeenranta, Kouvola
Doctors: Aino Karvonen, Tiina Korhonen, Maaria Viitasalo, Heli Siljander, Heli Yli-Jyrä, Tiina Karppa, Pauli Riikonen, Kaija Westergård, Niklas Lindblad, Krista Mykrä, Dmitrij Kruglikov, Pauli Ylitalo, Leila Mikkilä, Jussi Ojanperä, Vesa Vähäsarja , Arja Sokka, Tuomas Tocklin, Annika Lönnberg, Helena Lauren

A Phase II, Randomized, Observer-Blind, Active Controlled, Multi-center, Dose Ranging Study to Evaluate the Immunogenicity and Safety of Different Formulations of Chiron Conjugate Meningococcal ACWY Vaccine and Chiron Conjugate Meningococcal C Vaccine (Menjugate R) administered to Healthy Toddlers Aged 12 – 16 Months.
A phase II study, **Chiron Vaccines / Remedium, Protocol V59P2**
June 2003 – January 2005, 537 children
Vaccine Research Clinics: Tampere, Pori, Turku, Espoo, Jyväskylä, Lahti, Vantaa, Kuopio, Oulu
Doctors: Aino Karvonen, Tiina Korhonen, Pauli Riikonen, Jonna Maunu, Niklas Lindblad, Mirjami Aaltonen, Heli Siljander, Sirkka Parry, Tiina Karppa, Anneli Pere, Arja Sokka (Hynninen), Leila Mikkilä

Study of the Efficacy, Safety, and Immunogenicity of RotaTeq at Expiry Potency
A phase III study, **Merck & Co., Inc, Protocol 007**
November 2002 – 2003, 493 children
Vaccine Research Clinics: Tampere, Pori, Turku
Doctors: Aino Karvonen, Tiina Korhonen, Pauli Riikonen, Jonna Maunu

A Prospective, Randomized, Double-blind, Placebo-Controlled Trial to Assess Safety, Efficacy, Tolerability and Immunogenicity of Influenza Virus Vaccine, Trivalent, Types A&B, Live, Cold-Adapted, Liquid Formulation (CAIV-T), Administered Conco**mitantly with a Combination Live, Attenuated, Mumps, Measles and Rubella Vaccine in Healthy Children 11-24 Months.**
A phase I study, Wyeth Lederle Vaccines, Protocol D153-P522
September 2002 – May 2003, 200 children
Vaccine Research Clinics: Tampere, Lahti, Pori, Turku, Jyväskylä
Doctors: Aino Karvonen, Tiina Korhonen, Tiina Karppa, Pauli Riikonen, Jonna Maunu, Sirkka Parry

A Prospective, Randomized, Open-label, Controlled Trial to compare the Safety, Tolerability and Efficacy of Influenza Virus Vaccine, Trivalent, Type A&B, Live, Cold-Adapted (CAIV-T) with Influenza Virus Vaccine, Trivalent, Inactivated (TIV) in Children with Asthma aged 6 to 17 years.

A phase I study, **Wyeth Lederle Vaccines, Protocol D153-P515**
September 2001 – May 2002, 22 children
Vaccine Research Clinics: Tampere (TAYS)
Doctors: Anssi Luoma, Marita Paassilta

A Prospective, Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Safety and Tolerability of Influenza Virus Vaccine, Trivalent, Types A & B, Live Cold Adapted (CAIV-T) in Healthy Infants.
A phase I study, **Wyeth Lederle Vaccines / MedFiles, Protocol D153-P518**
September 2001 – November 2002 (120 children)
Study sites: Tampere, Espoo, Lahti, Pori, Turku, Jyväskylä

A phase II, open, controlled clinical study to assess the immunogenicity, reactogenicity and safety of a 2nd dose of SmithKlineBeecham Biologicals' measles-mumps-rubella-varicella (MeMuRu-OKA) vaccine given in healthy children of 5 to 6 years of age.

A phase II study, GSK, Protocol MeMuRu-OKA-017
2001 (92 children)
SmithKlineBeecham Biologicals
Study site: Tampere

A Prospective, Randomized, Double-Blind, Placebo-Controlled Trial to Determine the Safety and Efficacy of Influenza Virus Vaccine, Trivalent, Types A & B, Live cold-Adapted (CAIV-T) in Healthy Children Attending Day Care Centers.
A phase III study, **Wyeth Lederle Vaccines / MedFiles, Protocol D153-P502**
October 2000 – November 2001 (481 children)
Second year: 2001-2002
Study sites: Tampere, Espoo, Lahti, Pori, Jyväskylä

Safety and Efficacy of Pentavalent (G1, G2, G3, G4, and P1) Human-Bovine Reassortant Rotavirus Vaccine in Healthy Infants.
A phase III study, **Merck & Co., Inc, Protocol 006**
Nov 2000 – Nov 2004 (Last recruitment date 15 August 2003) 23 444 infants
Study sites: Tampere, Nokia, Valkeakoski, Espoo/Tapiola, Espoon Keskus, Espoonlahti, Kirkkonummi, Lohja, Lahti, Pori, Turku, Jyväskylä, Oulu, Kokkola, Vaasa, Pori, Seinäjoki, Rauma, Kuopio, Varkaus, Mikkeli, Lappeenranta, Kouvola, Kotka, Järvenpää, Riihimäki, Hyvinkää, Nurmijärvi, Vantaa West, Vantaa East, Helsinki North, Helsinki South, Helsinki East, Porvoo
Doctors: Merimaaria Espo, Aino Karvonen, Tiina Korhonen, Ulla-Kaisa Mickos, Anssi Luoma, Mirjami Aaltonen, Arja Heikkinen, Anne Sarajuuri, Kirsi Isoherranen, Heli Siljander, Tiina Karppa, Jukka Majuri, Pauli Riikonen, Leila Pajula, Marketta Juntunen, Eila Heikkilä, Teija Heikkinen, Kaija Westergård, Janne Vehanen, Marika Grönroos, Jonna Maunu, Krista Mykrä, Niklas Lindblad, Samuli Ylitalo, Leila Mikkilä, Vesa Vähäsarja, Christer Häggqvist, Jussi Ojanperä, Anne Kotaniemi-Syrjänen, Arja Sokka, Tuomas Toklin, Annika Löndberg, Helena Laurent, Anna-Liisa Kotsalainen, Pirjo Laitinen, Leena Kujala, Heta Khary, Johanna Khan, Anneli Pere, Sirpa Sairanen, Saeed Khan, Karl Lönnberg, Jonas Bondestam, Olle Nyblom, Panu-Pekka Pohjola, Maari Cederberg, Heta Haaslahti, Mirkka Lumia, Elina Koskikallio, Johanna Anttila-Bosdestam, Ashraf Benyamin

A phase IIb, double-blind, randomized, placebo-controlled study to assess the efficacy, immunogenicity, reactogenicity and safety of two doses of SB Biologicals' oral live attenuated human rotavirus (HRV) vaccine in healthy infants approximately 2 months of age and previously uninfected with human rotavirus
A phase IIb study, **Protokol GSK (SmithKlineBeecham Biologicals) Rota 004**
1.10.2000-15.9.2002 (405 infants)
Study sites: Tampere, Espoo, Lahti, Pori, Turku, Jyväskylä

A phase II, double-blind, randomized, placebo-controlled, dose-escalating, stepwise study to assess safety, reactogenicity and immunogenicity of SB Biologicals' live attenuated human rotavirus (HRV) vaccine in healthy infants previously uninfected with human rotavirus
A phase II study, **GSK (SmithKlineBeecham Biologicals), Protocol Rota 003**

1.4.2000-4.12.2000 (192 infants)
Study sites: Tampere, Espoo

A Randomized, Double-Blind Trial of the Safety, Transmissibility, and Phenotypic and Genotypic Stability of Influenza Virus Vaccine, Trivalent, Types A & B, Live cold-Adapted (CAIV-T) in Children Who Attend Day Care.
A phase III study, **Wyeth Lederle / MedFiles, Protocol D153-P500**
October 1999 – November 2000, Tampere 146, Turku 60 (206 children)
Study sites: Tampere, Turku

Protocol 005-001 Safety, Immunogenicity, and Efficacy in Healthy Infants of G1, G2, G3, G4, and P1 Human-Bovine Rotavirus Reassortant Vaccine.
A phase IIb study, **Merck, Protocol rota 005**
January 1998 – September 2000 (1300 + 646 children)
Study sites: Tampere, Espoo, Lahti, Pori

A phase II, double-blind trial of the safety and immunogenicity and efficacy of tetravalent bovine rotavirus vaccine (BV-TV) and tetravalent rhesus rotavirus vaccine (RV-TV).
A phase II study, **Wyeth-Lederle Vaccines and Pediatrics, Protocol D127-P801**
May 1997 – August 1998 (510 children)
Study sites: Tampere ja Lahti

RRV-TV (Rhesus-human reassortant tetravalent) rotavirus vaccine for newborns. Placebo controlled.
A phase I study, **Wyeth-Lederle Vaccines and Pediatrics, Protocol D127-P500**
June 1997 – August 1998 (94 children)
Study sites: TAYS (children and maternity wards)