Protection against HPV

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29611

Source
NTR

Brief title
HPV-2D

Health condition

Vaccination, HPV, Immunogenicity, Two-dose schedule

Vaccinatie, HPV, immunogeniciteit, twee-doses schema

Sponsors and support

Primary sponsor: National Institute for Public Health and The Environment, Bilthoven, the Netherlands
Source(s) of monetary or material Support: Dutch Ministry of Health, Welfare and Sports

Intervention

Outcome measures

Primary outcome

Cohort 1997-2000

- Antibody responses of vaccine-induced types after a two dose schedule up to 4 1/2 years after the first dose.

Cohort 2001

- Level and kinetics of vaccine-induced antibody response after a two dose schedule at approximately 7,12 and 24 months.

Secondary outcome

Cohort 1997-2000

- Cross-protection

Cohort 2001

- Avidity of antibodies

- Cross-protection

- Cellular immunity

Study description

Background summary

Rationale:

The change from three- to two-dose schedule for HPV vaccination asks for monitoring of the kinetics of vaccine induced
antibodies over time and of quality of vaccine-induced antibodies and cellular
immunity after a two-dose schedule.

Objective:

- To study the level and quality of antibody response at approximately 7, 12 and 24 months following the first dose of HPV-16/18 vaccination in a two-dose schedule and check whether this level remains above plateau.

- To study whether antibody responses involved in a two-dose HPV-16/18-vaccination schedule compared to a three-dose schedule, are non-inferior at approximately 1 ½, 2 ½, 3 ½ and 4 ½ years after the first dose.

Study design:

In a prospective cohort study cellular immunity, the level and quality of vaccine-induced antibodies will be studied in girls born in 2001 who were vaccinated by a two-dose schedule in 2014. Cross-sectional observational sampling will be performed among girls born between 1997 and 2000, to compare the vaccine-induced antibody levels and avidity after a two-dose schedule with a three-dose schedule.

Study population:

Girls born in 2001 who received a two-dose schedule and girls born between 1997 and 2000 who received either two or three doses of the bivalent HPV vaccine.

Main study parameters/endpoints:

- Type specific antibody levels against HPV types 16,18 in serum following the two-dose schedule and whether these levels remains above plateau for HPV-16/-18 up to 24 months after the first dose

- Kinetics of type specific antibody levels against HPV types 16,18 in serum following the two-dose schedule up to 24 months after the first dose

- Whether the two-dose schedule is non-inferior with regard to HPV16/18 antibody levels to the three-dose schedule up to approximately 4 ½ years after the first dose

Study objective

Antibody responses after a two-dose HPV vaccination schedule are non-inferior to a three-dose schedule.

Level of two-dose schedule antibodies remains above plateau.

Study design

Cohort 1997-2000

- 18, 30, 42, 54 months after the first dose

Cohort 2001

- 7, 12 and 24 months after the first dose

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Vaccinated with the bivalent HPV vaccine (Cervarix)

- Received two- (with at least five months interval) or three-doses (0,1,6 months) of the vaccine

- Born between 1997 and 2001

- Female

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Unknown or incorrect address

- Deceased

- Participated in tolerability study and stated to be no longer approachable for further research

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	418
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-08-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53042
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4578
NTR-old	NTR4719
CCMO	NL48754.029.14
OMON	NL-OMON53042

Study results