Early effects of Vaccine Immunisation (EVI) study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27917

Source
NTR

Brief title
EVI study

Health condition

Human Papillomavirus

Sponsors and support

Primary sponsor: Dutch Ministry of Health, welfare and Sports
Source(s) of monetary or material Support: Dutch Ministry of Health, welfare and Sports

Intervention

Outcome measures

Primary outcome

To obtain insight into signature of immune responses triggered
by a bivalent- or nonavalent HPV vaccination.

Secondary outcome

To determine the most informative time-points to study diff

Study description

Background summary

Rationale: Since 2009, the bivalent HPV vaccine was introduced in the National Immunisation Programme (NIP) for 12-year old girls. . The HPV vaccines are highly efficacious in preventing HPV related diseases. However, the early/rapid immune responses to HPV vaccines are not fully investigated yet. This study will investigate the early signature of immune responses of HPV vaccines.
Objective: Primary objective: To obtain insight into signature of immune responses triggered by a bivalent- or nonavalent HPV vaccination.
Secondary objectives: To determine the most informative time-points to study different innate
and adaptive immune subsets by tracking their expansion after vaccination.
Study design:
This study consists of a time finding study (Part I) and a longitudinal intervention study: baseline and follow-up measurements of immune parameters (Part II).
Study population:
Part I and Part II: The study population will consist of healthy, pre-menopausal women who are seronegative forhigh-risk HPV vaccine types.
Intervention (if applicable):
Participants will receive three injections of either the bivalent (Cervarix®) or nonavalent (Gardasil9®) HPV vaccine. In Part I twelve venous blood samples will be drawn and in Part II eight venous blood samples will be drawn.
Main study parameters/endpoints:
Detailed analysis of innate and adaptive immune cells and their kinetics over time will be performed by the means of flow cytometry. In addition, a flow cytometry-based approach will be developed to identify antigen-specific memory B cells and plasma cells prior to analysis of their immunoglobulin receptors by means of high throughput sequencing.
Study will be finished after the last study visit of the last donor.

Study objective

To obtain insight into signature of immune responses triggered
by a bivalent- or nonavalent HPV vaccination.

Study design

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eight venous blood samples will be drawn.

Intervention

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Contacts

Public
RIVM
Hella Pasmans

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Scientific
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Eligibility criteria

Inclusion criteria

 Seronegative for hr-HPV vaccine types(16,18,31,33,45,52,58)
 Female
 Normal general health
 Pre-menopausal
 Willing to receive HPV vaccination
 Provision of written informed consent
 Willing to adhere to the protocol and be available during the study period

Exclusion criteria

present evidence of serious disease(s) within the last 3 months before inclusion
requiring immunosuppressive or immune modulating medical treatment, such as
systemic corticosteroids, that might interfere with the results of the study;
 chronic infection
 known or suspected immune deficiency;
 history of any neurologic disorder, including epilepsy;
 previous administration of serum products (including immunoglobulins) within 6

months before vaccination and blood sampling
 known or suspected allergy to any of the vaccine components (by medical history)
 previous vaccination with any HPV vaccine
 pregnancy
 participating in another vaccination/ medicine study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-06-2019
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-05-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48227
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7736
CCMO	NL69015.100.19
OMON	NL-OMON48227

Study results