Early effects of Vaccine Immunisation

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Primary objective: To obtain insight into signature of immune responses triggered by a bivalent- or nonavalent HPV vaccination (three-dose schedule). Secondary objectives: To determine the most informative time-points to study different innate and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON48227

Source
ToetsingOnline

Brief title
Early Vaccine Immunization- study

Condition

- Viral infectious disorders

Synonym
human papillomavirus infection

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van Volksgezondheid;Welzijn en Sport

Intervention

Keyword: HPV, Immunology, Vaccines

Outcome measures

Primary outcome

To obtain insight into signature of immune responses triggered by a bivalent- or nonavalent HPV vaccination (three-dose schedule).

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.

Secondary outcome

To determine the most informative time-points to study different innate and adaptive immune subsets by tracking their expansion after vaccination.

Study description

Background summary

Since 2009, the bivalent HPV vaccine was introduced in the National Immunisation Programme (NIP) for 12-year old girls. However, also other vaccines are available to prevent HPV infections. Therefore, independent comparison between the bivalent and nonavalent HPV vaccination should take place on an immunological level to determine the differences and make an adequate vaccine decision for the Dutch population

Study objective

Primary objective: To obtain insight into signature of immune responses triggered by a bivalent- or nonavalent HPV vaccination (three-dose schedule).
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 out of a time finding study (Part I) and a longitudinal intervention study: baseline and follow-up measurements of immune parameters (Part II).

Intervention

Part I and II:Study particpants will either receive three-doses of the bivalent- (Cervarix) or nonavalent (Gardasil9) HPV vaccine.

Study burden and risks

Part I and Part II: Participants will benefit from participating in this study by receiving the vaccine they will be protected against future hrHPV infections. Although vaccination and especially venepunctures may be unpleasant, they are considered low risk invasive procedures. These risks will be mitigated by the performance of all procedures by experienced personnel. Cervarix® and Gardasil9® are both registered vaccines. Adverse reactions (ARs) to the vaccine may occur but they are expected to be mainly local and transient. Severe allergic reactions to one of the vaccine components are unlikely to occur.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Part I and Part II:
Healthy, pre-menopausal women who have not been vaccinated against HPV yet and are seronegative for high-risk HPV vaccine types

Exclusion criteria

Part I and II:Medical conditions that will severely affect immunological responses to
vaccinations, such as, but not limited to, cancer or an immune disorder.
Vaccination should be postponed during any illness with fever >38.5°C until the fever has disappeared.
An additional HPVvaccination during the study.
Coagulation disorder and/or anticoagulant medication.
Be or have been under immunosuppressive medical treatment, like cytostatics, high-dose corticosteroids, immune globulins, blood or plasma transfusions that might interfere with the results of the study (within the previous 3 months)., Had experienced a previous severe adverse reaction to any vaccine.
Being pregnant
Participating in another vaccine/ medicine study

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2019
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cervarix
Product type:	Medicine
Brand name:	Gardasil9

Ethics review

Approved WMO Date:	29-05-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27917
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2019-000253-31-NL
CCMO	NL69015.100.19
OMON	NL-OMON27917