

Randomised Controlled Study on the Effects of Imiquimod, a TLR 7 Activating Agent, on the HPV16-Specific Immune Response Following HPV16 E6/E.7 Synthetic Long Peptides Vaccination in Women with HPV16 Positive High Grade Vulvar/Vaginal Intraepithelial Neoplasia

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This study aims to compare the immunological response to vaccination with HPV16 E6 and E7 synthetic long peptides with concomitant application of imiquimod at the vaccination site with vaccination without the concomitant application of imiquimod.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21989

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

High grade vulvar and/or vaginal intraepithelial neoplasias which are HPV16 positive.

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)

Overige ondersteuning: In part funded by ISA Pharmaceuticals

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The immunological response to vaccination with HPV16 E6 and E7 synthetic long peptides with and without concomitant application of imiquimod at the vaccination site.

Toelichting onderzoek

Achtergrond van het onderzoek

Human Papilloma Virus (HPV)16 infection may cause vulvar intraepithelial neoplasia (VIN), and/or vaginal intraepithelial neoplasia, (VaIN). Vaccination with synthetic long peptides encoding for the oncogenes E6 and E7 from HPV16 may stimulate the immune system to eliminate the virus and associated lesions. This study will compare the immunological response after vaccination with and without the local application of imiquimod to the vaccination site. Also clinical response is measured up to 12 months after vaccination.

Doel van het onderzoek

This study aims to compare the immunological response to vaccination with HPV16 E6 and E7 synthetic long peptides with concomitant application of imiquimod at the vaccination site with vaccination without the concomitant application of imiquimod.

Onderzoeksopzet

- 3 weeks after second and last vaccination

- 3 and 12 months after last vaccination.

Onderzoeksproduct en/of interventie

All patients will be vaccinated four times with three week intervals with HPV16 E6 and E7 synthetic long peptides (ISA-HPV-01) at a dose of 300 µg /peptide in 2 separated subcutaneous injections.

Patients will be randomized to either: arm 1 is to receive local application of imiquimod on the vaccination sites one hour and 48 hours after each vaccination, arm 2 will not apply anything to the vaccination site.

Contactpersonen

Publiek

Leiden University Medical Center

Department of Gynaecology
 PO Box 9600
G. Kenter
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71-5263332

Wetenschappelijk

Leiden University Medical Center

Department of Gynaecology
 PO Box 9600
G. Kenter
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71-5263332

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients of 18 years and older.
2. Willing and able to comply with the protocol and to provide informed consent in accordance with institutional and regulatory guidelines.
3. Histological evidence of high grade VIN and/or VaIN, HPV16 positive.
4. Baseline laboratory findings; white blood cells (WBC) > 3,000 x 10⁹/l, lymphocytes > 1,000

x 10⁹/l, platelets > 100 x 10⁹/l.

5. HIV- and HBV-negative.

6. Patients of child-bearing potential should test negative using a serum pregnancy test and agree to utilize effective contraception during the entire treatment and follow-up period of the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known hypersensitivity to the vaccine or imiquimod or to any of the respective excipients.
2. Indication of a current active infectious disease of the vulva or other infections that need medical attention, other than HPV16.
3. VaIN lesions that are not distinguishable from a co-existing cervical intraepithelial neoplasia (CIN) lesion.
4. History of an autoimmune disease or other systemic intercurrent disease that might affect the immunocompetence of the patient, or patients receiving immunosuppressive therapy including transplant recipients.
5. History of a second malignancy except curatively treated low-stage tumours with a histology that can be differentiated from the vulvar, vaginal and cervical cancer type.
6. Radiotherapy, chemotherapy administered within 4 weeks prior to the enrolment visit.
7. Participation in a study with another investigational drug within 30 days prior to the enrolment in this study.
8. Any condition that in the opinion of the investigator could interfere with the conduct of the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	23-10-2008
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	06-11-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL681
NTR-old	NTR1526
Ander register	2007-005230-37 : HPV01/01
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A