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

No registrations found.

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

Summary

ID

NL-OMON21989

Source
Nationaal Trial Register

Brief title
N/A

Health condition

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

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)

Source(s) of monetary or material Support: In part funded by ISA Pharmaceuticals

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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

Study description

Background summary

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 elimintate 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.

Study objective

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.

Study design

- 3 weeks after second and last vaccination

- 3 and 12 months after last vaccination.

Intervention

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 ìg /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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-10-2008
Enrollment:	36
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-11-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results

N/A