

# A randomised, double-blind, placebo-controlled study to evaluate the efficacy of imiquimod 5% in women with vulvar intraepithelial neoplasia (VIN) stages two and three

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
11/10/2006	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
11/10/2006	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
15/04/2008	Cancer	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

N/A

## Study information

## Scientific Title

### Study objectives

Imiquimod, an immunomodulator, has been shown safe and effective in the treatment of external genital warts caused by low risk human papillomavirus (HPV). Therefore, it is hypothesised that this topical treatment may also be effective against different HPV types, and thus encourage regression of dysplastic vulvar lesions caused by high risk HPV.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the local medical ethics committee

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Vulvar Intraepithelial Neoplasia (VIN), vulvar dysplasia

### Interventions

After qualifying for study participation patients are randomly assigned to receive either 250 mg of imiquimod 5% cream (Aldara, 3M Pharmaceuticals, St Paul, MN, USA) or 250 mg of placebo cream.

Dosing will take place twice a week in the evening for a period of 16 weeks. A clinical assessment will take place every four weeks during treatment, and four weeks after final treatment. To investigate long-term effects and to exclude recurrence of VIN final assessments will take place after seven and 12 months.

A formalin fixed biopsy is taken for histological verification of VIN two/three within three months before the start of the study, together with a second biopsy from the same lesion frozen in liquid nitrogen for HPV deoxyribonucleic acid (DNA) testing. At 20 weeks a post-treatment biopsy is taken at exactly the same spot as the first biopsy to evaluate the histological effect, and again a frozen sample is taken for detection of HPV DNA. If a recurrence is suspected at 12 months a biopsy is taken again. In case of persistent or residual lesions after one year, the patient is offered treatment with imiquimod.

### Intervention Type

Drug

### Phase

Not Specified

**Drug/device/biological/vaccine name(s)**

Imiquimod

**Primary outcome(s)**

Reduction in lesion size

**Key secondary outcome(s))**

1. Histological regression
2. Clearance of HPV
3. Relief of clinical symptoms
4. Improvement of quality of life

**Completion date**

28/07/2005

## Eligibility

**Key inclusion criteria**

1. Histologically proven, multifocal VIN stage two or three without invasion
2. Age of 18 and older
3. Reliable method of contraception throughout the study

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Not Specified

**Key exclusion criteria**

1. Pregnancy
2. (Micro-)invasive carcinoma
3. History of vulvar cancer
4. Unifocal lesion
5. Any other treatment for VIN or anogenital warts within one month of start of trial
6. Hypersensitivity to any components of the cream
7. History of psoriasis or other inflammatory dermatosis of the vulva
8. Immunodeficiency
9. Insufficient command of the Dutch or English language

**Date of first enrolment**

26/04/2001

**Date of final enrolment**

28/07/2005

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

**The Netherlands Cancer Institute**

Amsterdam

Netherlands

1066 CX

## Sponsor information

**Organisation**

Erasmus Medical Center (The Netherlands)

**ROR**

<https://ror.org/018906e22>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Erasmus Medical Center (The Netherlands) - Department of Obstetrics and Gynaecology

**Funder Name**

3M Pharmaceuticals (USA)

**Funder Name**

Academic Medical Center (AMC) (The Netherlands) - Department of Obstetrics and Gynecology

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#"><u>Results article</u></a>	Results	03/04/2008		Yes	No