ISRCTN11290871 https://doi.org/10.1186/ISRCTN11290871

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
11/10/2006

Recruitment status
No longer recruiting

Registration date
11/10/2006

Overall study status
Completed

Last Edited
15/04/2008

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Reduction in lesion size

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

Overall study start date
26/04/2001

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
52

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)

Sponsor details
Department of Obstetrics and Gynecology
Dr. Molewaterplein 60
Rotterdam
Netherlands
3015 GJ

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	Results	03/04/2008		Yes	No