Topical 5% Imiquimod cream for vulvar Paget's disease: clinical efficacy, safety and immunological response

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To assess the efficacy, evaluate the safety and immunological effect of topical 5% imiquimod cream for vulvar Paget*s disease and the quality of life during treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vulvovaginal disorders (excl infections and inflammations)
Study type	Interventional

Summary

ID

NL-OMON42251

Source
ToetsingOnline

Brief title
Paget trial

Condition

- Vulvovaginal disorders (excl infections and inflammations)

Synonym
vulvar extramammary paget's disease; vulvar paget's disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Extramammary Paget's disease, imiquimod, vulva

Outcome measures

Primary outcome

The main outcome is the clinical response to treatment with topical 5% imiquimod cream, defined as a complete remission, partial remission or no remission. Complete remission is defined as disappearance of the lesion and histological confirmation of disappearance. Partial remission is defined as decrease by *50% of total lesion size. No response is defined as <50% decrease of total lesion size.

Secondary outcome

Secondary outcome is the safety of topical 5% imiquimod cream, assessed by recording all adverse events; immunological response will be assessed by different immunological markers (which are currently studied in a pilot trial) and the quality of life during treatment will be assessed by 3 questionnaires, EQ5D, DLQI and (if applicable) FSDS.

Study description

Background summary

Extra Mammary Paget*s disease (EMPD) is a rare skin tumour, usually of the genitalia in elderly women. Vulvar Paget*s disease is generally seen in postmenopausal, Caucasian women as an erythematous, eczematous, scaling or ulcerating plaque. Initial symptoms are irritation, burning, pain and a skin lesion. The origin of EMPD is not yet entirely understood. The treatment of choice is surgical excision, despite high recurrence rates. The mutilating consequences of surgery will lead to impressive morbidity in elderly women. To address this, a few studies have investigated the use of topical 5% imiquimod

cream for vulvar Paget*s disease. Topical 5% imiquimod cream seems to be a successful treatment option for a subset of women with vulvar Paget*s disease.

Study objective

To assess the efficacy, evaluate the safety and immunological effect of topical 5% imiquimod cream for vulvar Paget*s disease and the quality of life during treatment.

Study design

Prospective, multi-centre, observational, open-label, intervention study.

Intervention

All patients use topical 5% imiquimod cream 3 times a week for 16 weeks. In case of side effects patients are allowed to use lidocain ointment and/or painkillers, or to adjust the frequency to 2 times a week or to pause treatment for 1 week.

Study burden and risks

Before inclusion to this study, patients will have undergone a vulvar biopsy and mapping for diagnostic purposes. Vulvar Paget*s disease is associated with underlying carcinomas, additional mammography will be performed. After inclusion patients will visit the clinic 7 times and will have a consultation by phone once during treatment. The final check-up will take place 1 year after the end of treatment. Patients will undergo anogenital inspection, measurement and photo documentation at 3 separate visits. They will fill out 3 different questionnaires at 3 different times and record a patient diary at home. Patients will undergo a biopsy 3 times, twice as standard care for diagnostic purposes before and after treatment. An additional biopsy will be carried out 4 weeks after the start of treatment to evaluate the immunological effect of 5% imiquimod cream. Topical 5% imiquimod cream is registered for the use of condylomata acuminata and included patients will be treated accordingly, this schedule is also proven to be effective and safe in a randomized controlled trial for the treatment of usual vulvar intraepithelial neoplasia (uVIN). Based on these experiences it is considered a safe treatment and an attractive alternative for women with vulvar Paget*s disease instead of mutilating surgery.

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

- Non invasive vulvar Paget's disease, primary or recurrence after previous surgery
- Age 18 and older

Exclusion criteria

- invasive vulvar Paget's disease
- underlying adenocarcinoma
- previous treatment of the vulva with 5% imiquimod cream during the last 6 months
- patients with autoimmune disorders
- immune compromised patients
- pregnant women
- lactating women

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Aldara
Generic name:	Imiquimod
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-01-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-01-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-10-2015
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2014-005276-29-NL
ClinicalTrials.gov	NCT02385188
CCMO	NL51648.091.14

Study results

Date completed:	01-05-2018
Actual enrolment:	25