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A Randomised phase II multi-centre Trial of topical treatment in women with Vulval Intraepithelial Neoplasia

Submission date 03/09/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/09/2007	**Overall study status** Completed	
Last Edited 31/03/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-two-new-treatments-for-vulval-intraepithelial-neoplasia

Study website
http://www.wctu.org.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WCTU004; Sponsor ref: SPON CU 245

Study information

Scientific Title
A Randomised phase II multi-centre Trial of topical treatment in women with Vulval Intraepithelial Neoplasia (TR3-VIN)

Acronym
RT3-VIN

Study objectives
VIN is a pre-malignant condition that predominantly affects premenopausal women. VIN has a significant invasive potential, is often highly symptomatic and difficult to manage clinically. Severe distressing symptoms of itching and pain are common and management aims to both relieve symptoms and prevent malignant progression. The precise rate of malignant progression is unknown.

Surgery is often chosen as the treatment for this condition but is associated with high rates of recurrence and may be mutilating. By comparison, recent small studies of new topical treatments have shown promising results that warrant further investigation as an alternative to surgery.

The purpose of this research is to determine whether there is evidence that either of the topical treatments is active, safe and feasible to use and would therefore warrant further investigation in a phase III setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submitted as of 03/09/2007.

Study design
A randomised phase II multi-centre trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Vulval Intraepithelial Neoplasia

Interventions
Topical treatment with either imiquimod or cidofovir will be applied by the patient for a maximum of 24 weeks. In both treatments the patient should use as much cream as needed to adequately cover the affected area. Patients will be reviewed every 6 weeks. At each visit the lesion will be assessed. In the absence of complete response, treatment will be continued for a maximum of 24 weeks.

Arm A:
Topical imiquimod will be applied three times a week. A thin layer will be spread over the area at night and the area will be washed using aqueous cream and water the following day. Patients will be advised to avoid contact with the treated area, including avoiding sexual intercourse until the area is washed the next day.

Arm B:
Topical cidofovir will be applied three times a week. A thin layer will be spread over the area at night and the area will be washed using aqueous cream and water the following day. Patients will be advised to avoid contact with the treated area, including avoiding sexual intercourse, until the area is washed the next day.

Patients who are judged to have failed on either topical treatment will be given the opportunity to switch to the alternative trial treatment.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Histologically confirmed complete response by 30 weeks after start of treatment.

Secondary outcome measures
1. Symptomatic improvement, assessed at each 6-weekly visit
2. Compliance and side effects, assessed at each 6-weekly visit
3. Viral clearance, assessed 6 weeks after the participants stop treatment
4. Human PapillomaVirus (HPV) type and integration status, assessed 6 weeks after the participants stop treatment
5. Recurrence rate at two years (in 30 week complete responders). This will be assessed 6 monthly for 2 years from the end of treatment visit

Overall study start date
01/01/2008

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Women with biopsy proven Vulval Intraepithelial Neoplasia 3 (VIN3) (including visible peri-anal disease not extending into the anal canal)
2. At least one lesion of sufficient size to allow biopsies (greater than or equal to 1 cm2)
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
204 (102 in each arm)

Total final enrolment
180

Key exclusion criteria
1. Any patients with impaired renal function
2. Any patient with current anogenital carcinoma or any patient who, in the investigators opinion, is at a high risk of developing invasive disease (patients in whom invasive or microinvasive disease is suspected should have adequate biopsies to exclude this prior to entry)
3. Pregnancy, breast feeding or trying to conceive
4. Active treatment for VIN within the previous four weeks
5. Patients who are under 18 years old
6. Known allergy to either of the topical treatments
7. Unable to comply with protocol treatment
8. Prior failure of imiquimod or cidofovir following treatment 3 times a week for a minimum of 12 weeks

Date of first enrolment
01/01/2008

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

Department of Obstetrics and Gynaecology
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Sponsor information

Organisation
Cardiff University (UK)

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Sponsor type
University/education

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (C10087/A7736)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/11/2014		Yes	No
Results article	long-term follow-up results	01/08/2018	05/08/2019	Yes	No
Plain English results			31/03/2022	No	Yes