

A trial investigating the use of Veregen (EPIgallocatechin-3-gallate) in the treatment of Vulval Intraepithelial Neoplasia

Submission date 17/12/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/11/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/trials/a-trial-veregen-cream-vulva-intraepithelial-neoplasia-epivin>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2013-003107-19

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

15759

Study information

Scientific Title

Phase II clinical trial investigating the use of EPIgallocatechin-3-gallate (Veregen) in the treatment of Vulval Intraepithelial Neoplasia

Acronym

EPIVIN

Study objectives

The aim of this early phase trial is to determine if Veregen is a tolerable treatment with a level of activity that warrants further investigation in a definitive phase III trial. The trial will include women with histological diagnosis of VIN3 (usual type) and who have not received any prior treatment in the preceding 4 weeks.

The primary objective of the trial is to determine whether topical application of epigallocatechin-3-gallate (Veregen) can induce histological resolution of VIN when assessed 32 weeks following the start of treatment.

The secondary objectives of the trial are to supplement the primary outcome with analyses of objective response, patient safety, drug compliance and acceptability, need for further treatment, and quality of life.

More details can be found at: <http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=15759>

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East Midlands - Derby, 20/12/2013, ref: 13/EM/0398

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Gynaecological Cancer; Disease: Vulva

Interventions

1. Experimental arm, Veregen 10%
2. Placebo

Study Entry: Single Randomisation only

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Epigallocatechin-3-gallate (Veregen)

Primary outcome measure

Primary Outcome; Timepoint(s): 32 weeks

Secondary outcome measures

Secondary outcome measures; Timepoint(s): 2, 4, 8, 16, 32 and 52 weeks

Overall study start date

01/01/2014

Completion date

30/11/2018

Eligibility**Key inclusion criteria**

1. Female ≥ 18 years of age
2. Histological confirmation of 'usual' type vulval intraepithelial neoplasia (VIN3)*
3. At least one lesion that can be accurately measured (using the RECIST 1.1 criteria) in at least one dimension with longest diameter ≥ 20 mm
4. Using a reliable method of contraception (excluding condoms)
5. Written informed consent to participate in the trial

* All histological material generated by this study will be assessed by Specialist Consultant in Gynaecological Pathology, 10% of biopsies will be independently reviewed by a second pathologist

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Planned Sample Size: 56; UK Sample Size: 56

Total final enrolment

26

Key exclusion criteria

1. Suspected anogenital carcinoma or those considered by the attending clinician to be at high risk of developing invasive disease
2. Pregnant, breastfeeding or trying to conceive
3. Treated for VIN within the previous four weeks
4. Known allergy to Veregen or any of its components
5. Patients suffering from immunosuppressive disorder or taking immunosuppressives
6. Unable to comply with the protocol

Date of first enrolment

01/01/2014

Date of final enrolment

10/05/2017

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Cancer Research UK Clinical Trials Unit

Birmingham

United Kingdom

B15 2TT

Sponsor information**Organisation**

University of Birmingham (UK)

Sponsor details

Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type

University/education

ROR

<https://ror.org/03angcq70>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research (NIHR) (UK)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal by around 30/11/2019.

Intention to publish date

01/09/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	results		28/05/2020	No	No
Results article		08/11/2020	18/11/2020	Yes	No
Plain English results		04/11/2021	11/11/2021	No	Yes
HRA research summary			28/06/2023	No	No