ISRCTN98495886 https://doi.org/10.1186/ISRCTN98495886

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/12/2013	**Overall study status** Completed	
Last Edited 11/11/2021	**Condition category** Cancer	

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
Miss Baljit Kaur

Contact details
Cancer Research UK Clinical Trials Unit
School of Cancer Sciences
Edgbaston
Birmingham
United Kingdom
B15 2TT
-
b.kaur@bham.ac.uk

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 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			28/05/2020	No	No
Results article	results	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