ISRCTN88589234 https://doi.org/10.1186/ISRCTN88589234

PREMIUM (PRE-Surgical Metformin In Uterine Malignancies) study

Submission date	Recruitment status	[_] Prospectively registered
04/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/03/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/07/2019	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-metformin-before-surgery-for-womb-cancer

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2014-000991-25

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17351

Study information

Scientific Title
Presurgical metformin for women with endometrial cancer: a randomised placebo controlled trial

Study objectives
Randomised placebo-controlled trial looking to determine whether metformin inhibits cellular growth in endometrial cancer and severe atypical endometrial hyperplasia. It will also look at the biological effects of metformin in endometrial cancer and hyperplasia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North west-Haydock, 23/09/2014, ref: 14/NW/1236

Study design
Randomised; Interventional; Design type: Treatment

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 contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Gynaecological Cancer; Disease: Uterus/Endometrium

Interventions
Metformin 850mg or placebo given once daily for 3 days and then twice a day until surgery

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Metformin

Primary outcome measure

Tumour analysis - Ki-67; Timepoint(s): screening and pre operative

Secondary outcome measures
1. Physiological analyses - insulin resistance and obesity markers; Timepoint(s): Screening and pre operative
2. Tolerability of treatment; Timepoint(s): pre operative
3. Tumour analysis - Apoptotic markers; Timepoint(s): screening and pre operative
4. Tumour analysis - PI3K-Akt-mTOR signal transduction pathway molecules; Timepoint(s): screening and pre operative

Overall study start date
06/02/2015

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Biopsy-proven type 1 endometrial carcinoma or severe atypical endometrial hyperplasia
2. Scheduled surgical treatment by hysterectomy in 5-35 days' time
3. Informed consent
4. Age 18 years or more

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Key exclusion criteria
1. Current treatment with metformin
2. Diabetic on hypoglycaemic medication
3. Inability to consent due to lack of capacity or language barriers
4. Unable to comply with treatment protocol
5. Type 2 endometrial cancer
6. Severe renal impairment (Serum creatinine >130umol/L or eGFR < 45ml/min/1.732m2)
7. Severe hepatic impairment (abnormal LFTs to be discussed on case by case basis with hepatologist)

8. Current alcohol abuse
9. Sensitivity/hypersensitivity to biguanides
10. Current treatment with other mTOR inhibitors or chemotherapeutic agents

Date of first enrolment
06/02/2015

Date of final enrolment
02/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Central Manchester Foundation Trust (lead site)
Manchester
United Kingdom
M13 9WL

Study participating centre
Wrightington, Wigan and Leigh NHS Foundation Trust
Wigan, Lancashire
United Kingdom
WN1 2NN

Study participating centre
Christie Hospital NHS Foundation Trust
Manchester
United Kingdom
M20 4BX

Study participating centre
Pennine Acute Hospitals NHS Trust
Manchester
United Kingdom
M8 5RB

Study participating centre
Tameside General Hospital
Ashton-under-Lyne
United Kingdom
OL6 9RW

Sponsor information

Organisation
Central Manchester University Hospitals NHS Trust (CMFT)

Sponsor details
Genetic Medicine, Manchester Royal Infirmary
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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
Upon completion the study will be published in peer reviewed, open access journals in order to increase the dissemination of the results generated. It will also form the basis for a thesis to be put forward for the award of a PhD at the University of Manchester and will be available to be viewed in this format. The results of the study will also be presented at national and international meetings to inform both clinicians and scientists with an interest in endometrial cancer. An abstract submission is being prepared for presentation at the European Gynaecological Oncology Congress in November 2017, submission to journals is likely to be in early 2018. Patients recruited to the study will be informed of the trial results and public engagement events will be undertaken to increase awareness of the study's findings within the lay population.

Intention to publish date
30/04/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Lynne Webster (lynne.webster@cmft.nhs.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/04/2019		Yes	No
Plain English results			18/07/2019	No	Yes
HRA research summary			28/06/2023	No	No