

PREMIUM (PRE-Surgical Metformin In Uterine Malignancies) study

Submission date 04/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/07/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

Mr Richard Hutson

Contact details

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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 $>130\mu\text{mol/L}$ or $\text{eGFR} < 45\text{ml/min/1.732m}^2$)
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

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