

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

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2014-000991-25

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Treatment

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

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)

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

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
HRA research summary			28/06/2023	No	No
Plain English results			18/07/2019	No	Yes