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Quality of life after surgery and other options to prevent cancer of the lining of the womb (endometrial cancer)

Submission date 10/11/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/12/2022	**Overall study status** Completed	
Last Edited 07/02/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
The PRESCORES study is designed to help prevent cancers of the lining of the womb (also called endometrial cancer). Some women are at increased risk of womb cancer. This includes women with Lynch Syndrome, who are at very high risk. Those people may have surgery to remove the womb to prevent this cancer. This surgery is called "risk-reducing hysterectomy". It is unknown whether other people who are not at such high risk of womb cancer as women with Lynch Syndrome would also benefit from this surgery.

The aim of this study is to understand the quality-of-life of women who have risk-reducing hysterectomy. Once we understand this, we can use health economic modelling to work out who else would benefit from this surgery. We want to find out how high a person's lifetime risk of womb cancer must be for this surgery to be beneficial, and cost-effective. After finding this out, we want to see whether people from the general population would find it acceptable to be offered a risk-reducing hysterectomy, if they found out that they had an increased risk of womb cancer.

Who can participate?
Women with Lynch Syndrome who live in the UK can participate in this part of the study. They must be over 18 years of age.

What does the study involve?
Participants who wish to join the study will complete a short consent form, before completing a questionnaire. This questionnaire asks for some background medical information, the quality of life of participants, cancer worry, and certain demographic questions. This questionnaire takes around 10-15 minutes to complete. Participants completing the study on paper must return the completed consent form and questionnaire in an enclosed self-addressed freepost envelope. Participants completing the study online will simply submit when finished. After this, there is no further involvement of participants in the study.

What are the possible benefits and risks of participating?
There are unlikely to be immediate benefits from participating in this study, except for the satisfaction of having contributed towards this research on endometrial cancer prevention. Participants, along with other women at risk of endometrial cancer, may benefit from the knowledge gained in this study if they are considering risk-reducing surgery to prevent endometrial cancer in future.

As this is a questionnaire-based study there are few risks to participants. Potential participants may find it difficult to complete the study due to the sensitive or personal nature of some questions (eg regarding cancer risk and medical history). They are free to not continue or withdraw from the study at any time without giving a reason. Information about support charities such as Lynch Syndrome UK is provided.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
January 2022 to January 2025

Who is funding the study?
RoseTrees Trust (UK)

Who is the main contact?
Professor Ranjit Manchanda, r.manchanda@qmul.ac.uk

Study website
https://www.prescores.co.uk/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
280449

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 280449, CPMS 54165

Study information

Scientific Title

Prevention of endometrial cancers: comparing risk-reducing strategies

Acronym
PRESCORES

Study objectives
This study will determine who would benefit from preventive strategies for endometrial cancer. It will obtain measures of health-related quality of life (called utility scores) for risk-reducing hysterectomy performed for endometrial cancer prevention.
These utility scores will then be used in health economic modelling, called cost-utility analysis. This will determine the lifetime individual risk of endometrial cancer at which someone would benefit from risk-reducing hysterectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 05/12/2022, London - Surrey Research Ethics Committee (Nottingham Centre, Nottingham, NG1 6FS, United Kingdom; N/A; surrey.rec@hra.nhs.uk), ref: 22/PR/1167
2. Approved 05/10/2022, Surrey Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 1048 088; surrey.rec@hra.nhs.uk), ref: 22/PR/1167

Study design
Multicentre questionnaire-based cross-sectional cohort survey

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Lynch syndrome

Interventions
Potential participants will be contacted by their usual treating team, or via support charities such as Lynch Syndrome UK (for individuals who have previously voluntarily signed up to such mailing lists).
This can be either via post or online. They will be able to read a simple summary page about the study (cover letter).
For potential participants reading this online wishing to progress, they must first complete a

very short screening questionnaire to establish eligibility. This will not be necessary for potential participants receiving paper copies as they will have been screened by their treating clinical team.
Potential participants will be able to read the Participant Information Sheet.
If an individual wishes to participate, they must sign the study consent form. They may then complete the study questionnaire.
Participants who complete the study on paper must return the signed consent form and completed questionnaire in the enclosed self-addressed freepost envelope.
This ends the involvement of participants in this study.

Intervention Type
Other

Primary outcome measure
Health-related utility scores for risk-reducing hysterectomy for endometrial cancer prevention, measured using EQ-5D questionnaire at baseline

Secondary outcome measures
1. Variables predictive for risk reducing hysterectomy, measured using a customised questionnaire alongside EQ-5D at baseline
2. Separate health-related utility scores for pre and post-menopausal patients undergoing risk-reducing hysterectomy with and without ovarian conservation, measured using a customised questionnaire alongside EQ-5D at baseline
3. Endometrial cancer risk threshold for undergoing risk-reducing hysterectomy, using Markov modelling to perform cost-utility analysis, following collection of EQ-5D data.
4. Cost-effectiveness of risk-reducing hysterectomy, using Markov modelling to perform cost-utility analysis, following collection of EQ-5D data. 2. Costs will be measured using a UK public healthcare system (payers) perspective, with values derived from the literature. A lifetime horizon will be used with appropriate discounting. Cost-effectiveness will be calculated using the incremental cost-effectiveness ratio (ICER), and compared against the willingness-to-pay threshold from the UK National Institute of Health and Care Excellence of £20,000 - £30,000 per quality-adjusted life year (QALY).

Overall study start date
01/01/2022

Completion date
01/01/2025

Eligibility

Key inclusion criteria
1. Female
2. Age >18 years old
3. Lynch Syndrome diagnosis - confirmed germline mutation in MLH1, MSH2, MSH6, PSM2, ECPAM
4. UK Resident

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
750

Key exclusion criteria
1. Unwilling or unable to provide informed consent
2. Inability to understand written and verbal English

Date of first enrolment
13/06/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Joint Research Management Office (JRMO)
Research Services

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Sponsor type
University/education

Website
http://www.jrmo.org.uk/about-us/contact-us/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Rosetrees Trust

Alternative Name(s)
Teresa Rosenbaum Golden Charitable Trust, Rosetrees

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal, and presentation at national and international conferences

Intention to publish date

01/01/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Ranjit Manchanda (r.manchanda@qmul.ac.uk). Anonymised data can be shared upon reasonable request, containing no identifiable information such as name or date of birth. This would be potentially available after study completion, from 2025 onwards, or after publication of results (whichever comes first). Written consent from all participants is required and is obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0		07/02/2024	No	No