Anxiety and Distress Levels in Women with Suspected Endometrial Cancer

MAIN SPONSOR: Imperial College London
STUDY COORDINATION CENTRE: Hammersmith Hospital
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Study Management Group

Chief Investigator: Miss Sadaf Ghaem-Maghami (gynaecological oncology consultant)

Miss Diana Marcus (clinical research fellow)

Clinical Queries

Clinical queries should be directed to Dr Diana Marcus Clinical Research Fellow, who will direct the query to the appropriate person

Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Joint Research Compliance Office
Imperial College London & Imperial College Healthcare NHS Trust
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Funder

This protocol describes the aforementioned study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

Table of Contents

GLOSSARY OF ABBREVIATIONS

PMB	Post menopausal Bleeding
IMB	Intermenstrual Bleeding

KEYWORDS

Innovations
Endometrial
Cancer
Psychological
Anxiety

STUDY SUMMARY

TITLE Anxiety of women attending rapid access clinic with suspected endometrial cancer

DESIGN Prospective observational study and study

AIMS (1) Determine the anxiety levels of women with suspected endometrial cancer
(2) Determine factors affecting anxiety levels

OUTCOME MEASURES Primary outcome measures:
(1) Anxiety levels of women with suspected cancer

Secondary outcome measures:
(1) Factors affecting anxiety level

POPULATION 250 women referred to rapid access clinic with postmenopausal bleeding or intermenstrual bleeding.

ELIGIBILITY All women presenting to rapid access gynaecology clinic with postmenopausal bleeding or intermenstrual bleeding

EXCLUSION Anyone lacking capacity. <18years old. Pregnant. Any contra-indication carry out a biopsy

DURATION 1 year

1. INTRODUCTION

1.1 BACKGROUND

Endometrial cancer is a tumour originating in the endometrium (womb lining); it is the most common gynaecological cancer in the UK. In 2012, there were almost 100,000 new cases diagnosed in Europe. The lifetime risk of developing endometrial cancer is 1.7%-2.6%. Endometrial cancer classically presents with postmenopausal bleeding (bleeding after the menopause), or intermenstrual bleeding (bleeding between periods).

It is well recognised, that cancer has a huge detrimental psychological effect. Few studies have investigated stress and anxiety levels in patients with suspected cancer, though it is assumed to be high.

1.2 RATIONALE FOR CURRENT STUDY

It is assumed that women attending rapid access clinics with suspected cancer are anxious and stressed but few studies have investigated this.

2. STUDY OBJECTIVES

Objectives:
(1) Determine the anxiety levels of women with suspected endometrial cancer
(2) Determine factors affecting anxiety levels

3. STUDY DESIGN

Paired observational study
Setting: Imperial College NHS Trust Hospitals, London
Participants: 250 women referred to rapid access clinic with postmenopausal bleeding or intermenstrual bleeding.
Duration: 1 year

3.1 MAIN STUDY

250 consecutive women presenting to the rapid access clinic with postmenopausal bleeding (PMB) and intermenstrual bleeding (IMB) will be approached for consent for inclusion into this study.
Women were given a short 5-minute questionnaire to fill during their first clinic attendance, before seeing any clinician or healthcare provider (see appendix for copy of questionnaire). The questionnaire had 19 questions, split into 4 broad groups: questions quantifying anxiety/stress levels, factors that might affect anxiety levels, patient's perception of cancer diagnosis and the importance of a quick diagnosis. Patients were asked to score how they perceived their stress levels using a Likert scale. A score of 4 or above was defined as high stress in this study and 3 and below as low stress. Patients were also asked to fill a Generalised Anxiety Disorder 7 (GAD 7) form.
Women were excluded if, in the absence of a translator, they did not have sufficient comprehension of English to fill the questionnaire. Patients were also excluded from the analysis if they omitted 3 or more answers from the questionnaire.

For women needing a pipelle biopsy for clinical indications, the time taken to perform the biopsy, from insertion of the speculum to its removal was recorded in minutes, rounded to the nearest 30 seconds. Women were asked to rank their pain using a visual analogue score (0 to 10, where 0 is no pain and 10 is the worst pain in their life). Women were asked if they would have this procedure again, if they would recommend it to family or friends should they were need it. If women persisted with the procedure, they were asked their motivations for doing so, and what coping mechanisms they used. This paired data was matched to the patient's questionnaire responses.

4. PARTICIPANT ENTRY

4.1 PRE-REGISTRATION EVALUATIONS

No need for any specific screening tests prior to participant entry into the study.

4.2 INCLUSION CRITERIA

All women presenting to rapid access gynaecology clinic with postmenopausal bleeding or intermenstrual bleeding

4.3 EXCLUSION CRITERIA

Anyone lacking capacity. <18years old. Pregnant. Any contra-indication carry out a biopsy

4.4 WITHDRAWAL CRITERIA

Withdrawal procedure occurs if patients choose to exit the study or if they loose capacity. The clinical details up till the point of withdrawal of the patient from the study will remain on file.

5. ADVERSE EVENTS

5.1 DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*

- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

5.3 REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.3.1 Non serious AEs

All such events, whether expected or not, should be recorded.

5.3.2 Serious AEs
An SAE form should be completed and faxed to the Chief Investigator within 24 hours. However, relapse and death due to endometrial cancer and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the JCRO at Imperial where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

6. ASSESSMENT AND FOLLOW-UP

Following the survey/biopsy will continue with routine standard of care and follow up.

End of trial will be defined as when the last patient for recruitment received her operative surgery (and final histology was obtained) and has been followed up for 5 years.

7. STATISTICS AND DATA ANALYSIS

Microsoft excel was used to provide the graphs and pie charts for demographics.
SPSS version 25 was used to perform all the sub analyses. Median, quartile ranges, box and whiskers plots were created for each variable. A Mann-Whitney-Wilcox test was used to assess for association between each factor and anxiety as measured with GAD 7 score.

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

8. REGULATORY ISSUES

8.1 ETHICS APPROVAL
The Chief Investigator has obtained approval from the Research Ethics Committee. The study must be submitted for Site Specific Assessment (SSA) at each participating NHS Trust. The Chief Investigator will require a copy of the Trust R&D approval letter before accepting participants into the study. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 CONSENT
Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage

if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

8.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

8.4 INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study/ Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Litigation Authority for NHS Trusts in England, which apply to this study (delete as applicable)

8.5 SPONSOR

Imperial College London/Imperial College Healthcare NHS Trust (delete as applicable) will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

8.6 FUNDING

We have applied for funding from the wellbeing of women charity.

8.7 AUDITS

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Dr Diana Marcus, clinical research fellow.

10. PUBLICATION POLICY

The data obtained from this study will be anonymised and analysed. The anonymised data will be published in peer-reviewed journals and presented in relevant conferences and at patient/public engagement events.