Plan Overview

A Data Management Plan created using DMPonline

Title: Endometrial Hyperplasia and Cancer: Exploring Potentials for Standardisation of Management and addressing gaps in clinical practice

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Template: UoB short template

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Project abstract:

Endometrial cancer is the fourth most common cancer in females in the United Kingdom. Endometrial hyperplasia is a pre-cancerous lesion. Atypical hyperplasia (AH) can progress to cancer as well as synchronously co-exist with endometrial malignancy in 28% and 42.6% of cases, respectively, while hyperplasia without atypia is associated with a risk of progression to cancer of less than 5%.

We aim to conduct two projects:

Project A: Risk of **C**ancer and **H**yperplasia in Thickened Endometrium Without Postmenopausal Bleeding – RiCH study.

A recent systematic review and meta-analysis study by our team highlighted the lack of evidence to inform clinical practice with regards to the optimal endometrial thickness (ET) threshold that discriminates normal endometrium from endometrial hyperplasia and cancer in postmenopausal women with no postmenopausal bleeding (PMB) and incidental finding of thickened endometrium >4 mm on a transvaginal scan (TVS) performed for other symptoms. We aim to conduct a well-designed multi-centre prospective study taking into account malignancy risk indicators to maximize the diagnostic accuracy of TVS. This is in order to produce evidence to inform clinical practice and enable an individualised approach to the management.

The primary objective of this study is to determine the optimal endometrial thickness (ET) threshold that might discriminate normal endometrium from endometrial hyperplasia and cancer in postmenopausal women with no PMB and an incidental finding of thickened endometrium >4 mm on TVS performed for other symptoms, taking into consideration common risk factors (age, BMI, parity, and type 2 diabetes mellitus) to maximise the diagnostic accuracy of TVS. In other words, to provide tailored ET threshold through developing a risk prediction model for endometrial hyperplasia and cancer in this group of women.

Project B: Evaluation of Conservative Management Practices and Missed Opportunities for Sentinel Node Sampling in Endometrial Atypical Hyperplasia and Early Low-Grade Cancer.

AH is a challenging condition to manage and is becoming a global health issue due to its rising incidence among young premenopausal women. Key areas of debate in AH management highlight critical gaps in current practice, including:

1. **Conservative management:** There is lack of consensus regarding theoptimal hormonal management of AH and low-grade endometrial cancer (EC).
2. **Underdiagnosis of concurrent EC at biopsy:** Accurate diagnosis is critical in managing AH, whether treated conservatively or surgically. Recent studies showed that hysteroscopic resection is the endometrial sampling method associated with the least underdiagnosis rates of concurrent EC in cases with AH as a preoperative diagnosis.
3. **Missed opportunities for sentinel lymph node biopsy (SLNB) at hysterectomy:** the potential risk of undertreatment of AH where a more radical approach would have been warranted for appropriate surgical staging, such as lymph node assessment.

This study primarily aims to evaluate whether the conservative management of AH and low-grade EC is standardised across different NHS centres as per the BGCS recommendations for conservative management. In addition, this study aims to identify the rate of missed diagnosis of concurrent EC on the initial biopsy compared to the final histopathology report. Lastly, we aim to quantify the number of cases with an initial diagnosis of AH where a more radical surgical approach, such as sentinel lymph node biopsy, would have been warranted to inform future clinical decisions.

ID: 184127

Start date: 07-10-2024

End date: 06-10-2026

Last modified: 31-08-2025

Grant number / URL: Sandwell and West Birmingham NHS Trust - Research Fellowship

Copyright information:

Endometrial Hyperplasia and Cancer: Exploring Potentials for Standardisation of Management and addressing gaps in clinical practice

Data description

What types of data will be used or created?

Project A: RiCH (Risk of Cancer & Hyperplasia in Thickened Endometrium without PMB)

- Prospective observational dataset drawn from gynaecology clinics at 10 + NHS trusts.
- Patient demographics: age, ethnicity, BMI.
- Patient identifying details: initials, NHS numbers, date of birth (accessbile only to respective local teams and database auditors)
- Clinical variables: menopausal status, parity, type 2 diabetes and other comorbidities, family history of malignancy
- Diagnostic data: ultrasound parameters (namely endometrial thickness, uterine and ovarian lesions), hysteroscopic findings.
- Pathology data: routine biopsy outcomes.

Project B: Conservative Management of Atypical Hyperplasia & Early Low-Grade Cancer

- Ambispective (retrospective 2015-2025 + prospective 2025-2026) multicentre service-evaluation project.
- Demographics & risk factors as above.
- Personal identifying details accessible only to local clinical teams.
- Clinical details: indication for biopsy, mode of sampling.
- Treatment data: conservative therapy regimen, adjuvant agents (ie metformin, weight-loss interventions), surgical treatment details if applicable.
- Outcome data: response to treatment, fertility outcomes if applicable, final hysterectomy histology if applicable.

How will the data be structured and documented?

Project A:

- All variables entered into standardised REDCap e-CRFs at each recruiting site.
- Personal identifiers (initials, NHS number, DOB) visible only to the local team and REDCap administrators.
- Consent can either by signed on REDCap as e-consent or on on paper.
- Once complete, the study ID only dataset is pseudo-anonymised and exported to a locked Excel workbook for cleaning and statistical analysis.

Project B:

- Data likewise captured in REDCap across all centres.
- Each site keeps its own Excel “linkage” sheet that holds identifiers. These sheets stay in the respective Trusts.

- After data collection is concluded, a deidentified REDCap export is produced, transferred to Excel, and cleaned for subsequent analyses.

Data storage and archiving

How will your data be stored and backed up?

Project A:

- Data is held in REDCap on University of Birmingham (UoB) secure servers. Encrypted backups copied to an off-site disaster-recovery location.
- Data entered into REDCap will be pseudonymised to further safeguard confidentiality. The dataset will be divided into two separate REDCap sheets:
  1. A main sheet containing de-identified demographic, clinical, sonographic, hysteroscopic, and histopathological data.
  2. A linkage sheet with initials, date of birth, and NHS number
- Access is role-based with Multifactor Authentication. All activity is logged.
- Study data will be retained for the duration of the study and for a period of five years after study completion, as per institutional policies and legal requirements. After this period, data will be securely deleted or archived in accordance with data retention protocols.

Project B:

- Anonymised data will be captured in REDCap with the same UoB backup system.
- Excel linkage sheets that hold identifying details stays in the respective Trusts
- Identifiers remain in a local password-protected spreadsheet. Only the anonymised dataset is transferred for data cleaning and analysis.
- Study data will be retained for the duration of the study and for a period of five years after study completion, as per institutional policies and legal requirements. After this period, data will be securely deleted or archived in accordance with data retention protocols.

Is any of the data of (ethically or commercially) sensitive nature? If so, how do you ensure the data are protected accordingly?

Project A:

- The study team will use the minimum personally identifiable information possible. If a participant withdraws from the study, we will keep the information about the participant that we have already obtained unless specifically asked to delete. However, if data has already been anonymised for statistical analysis, it will no longer be possible to delete the records, as anonymisation prevents any means of identifying individual participants within the dataset.

  Data entered into REDCap will be pseudonymised to further safeguard confidentiality.
  The dataset will be divided into two separate REDCap sheets:

  1. A main sheet containing de-identified demographic, clinical, sonographic, hysteroscopic, and histopathological data.

2. A linkage sheet with initials, date of birth, and NHS number.

Each participant will be assigned a unique study ID, which will securely link both sheets. Access to the linkage sheet will be strictly limited to the local principal investigator, study monitors, and REDCap study database host at University of Birmingham for database management purposes only if absolutely necessary. This two-sheet approach will ensure that participant data remains confidential, with restricted access and a secure separation of identifying information.

Project B:

- Anonymised data will be captured in REDCap with the same UoB backup system.
- Excel linkage sheets that hold identifying details stays in the respective Trusts
- Identifiers remain in a local password-protected spreadsheet. Only the anonymised dataset is transferred for data cleaning and analysis.

Where will your data be archived in the long term?

Study data will be retained for the duration of the study and for a period of five years after study completion as per institutional policies and legal requirements. Anonymised data will be stored on NHS One Drive (NHS Microsoft SharePoint). After this period, data will be either securely deleted or further archived in accordance with data retention protocols.

Data sharing

Which data will you share, and under which conditions? How will you make the data available to others?

Access to the full pseudonymised dataset is limited to the study-management group and the secure REDCap database host to prevent premature disclosure and keep analysis centrally coordinated.

Local investigators can view only the records collected at their own site.

Any request for the aggregated dataset (ie for secondary analysis) requires written approval from the management group and must be covered by the original participant-consent clause permitting future reuse.

The management group retains data ownership and publication rights. Individual centres may not publish their site data until the main results are released.

Final findings will be in peer-reviewed publications and conference presentations using fully anonymised aggregate data.