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A prospective randomised comparison of surgical treatment and expectant management of intrauterine polyps/fibroids in premenopausal women with abnormal uterine bleeding in an office hysteroscopy setting

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
19/08/2015

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0084125088

Study information

Scientific Title
A prospective randomised comparison of surgical treatment and expectant management of intrauterine polyps/fibroids in premenopausal women with abnormal uterine bleeding in an office hysteroscopy setting

Study objectives
To determine the effect of treatment on the symptoms experienced and to determine the natural history of polyps/fibroids in relation to the symptoms in patients who have intrauterine lesion in situ.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Polyps/fibroids

Interventions
Patients will be randomised preoperatively by a computer generated sequence into one of the two study arms: Hysteroscopic treatment or diagnostic hysteroscopy alone.
The control group will comprise of asymptomatic patients undergoing sterilisation who will have diagnostic hysteroscopy.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/12/2005

Eligibility

Key inclusion criteria
Women attending the clinic for routine check up.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
08/04/2003

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Castle Hill Hospital
Cottingham
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes