

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

☐ Prospectively registered

☐ Protocol

Registration date

30/09/2004

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

19/08/2015

Condition category

Urological and Genital Diseases

☐ 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

Primary study design

Interventional

Study design

Randomised controlled trial

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