ISRCTN71229651 https://doi.org/10.1186/ISRCTN71229651

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/04/2003

Completion date
01/12/2005

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration