ISRCTN06560767 https://doi.org/10.1186/ISRCTN06560767

A placebo controlled trial of medical treatment of submucous fibroids with gonadotropin releasing hormone (GnRH) analogues prior to hysteroscopic resection.

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
18/08/2010

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

N0116148335

Study information

Scientific Title

Study objectives
To evaluate whether pre-operative treatment with gonadotropin releasing hormone (GnRH) analogues prior to hysteroscopic resection of submucous fibroids increases the success of surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double blind randomised placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Gynaecological

Interventions
Women undergoing TCRM will be randomised to receive pre-operative treatment with gonadotropin releasing hormone (GnRH) or placebo.
The duration of follow up was 6 weeks, post operatively

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

gonadotropin releasing hormone (GnRH)

Primary outcome measure
Added 18/08/10:
Completeness of fibroid resection

Secondary outcome measures
Added 18/08/10:
1. Duration of the TCRM
2. Fluid deficit recorded at TCRM
3. Resolution of symptoms post-operatively
4. Number of subsequent fibroid related operations

Overall study start date
01/02/2003

Completion date
01/12/2006

Eligibility

Key inclusion criteria
Added 18/08/10:
1. Women found to have submucous fibroids on three-dimensional saline infusion sonohysterography (3D SIS)
2. Removal of fibroids by hysteroscopic transcervical resection of myoma (TCRM)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
47 (added 18/08/10; see publication)

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/02/2003

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Obstetrics and Gynaecology
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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SW1A 2NL
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Sponsor type
Government

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Kings College Hospital NHS Trust R&D Consortium (UK) - NHS R&D support funding

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2010		Yes	No