

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/08/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

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SE5 9RS

Sponsor information

Organisation

Department of Health

Sponsor details

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dhmail@doh.gsi.org.uk

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