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# A placebo controlled trial of medical treatment of submucous fibroids with Gonadotrophin Releasing Hormone (GnRH) analogues prior to hysteroscopic resection

**Submission date**
23/08/2005

**Recruitment status**
No longer recruiting

**Registration date**
30/11/2005

**Overall study status**
Completed

**Last Edited**
15/05/2012

**Condition category**
Urological and Genital Diseases

[_] 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**
N/A

# Study information

## Scientific Title

## Study objectives
Submucous fibroids are benign tumours of the smooth muscle cells of the uterus. They are found in at least 20 - 25% of women over the age of 35 years although they may be as frequent as 50%. Fibroids are the most common identifiable cause of excessive menstrual blood loss in reproductive age.

Hypothesis:
To evaluate whether preoperative treatment with 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
Randomised double blind placebo controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## 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
Submucous fibroids

## Interventions
This randomised double blind placebo controlled trial will include women referred for ultrasound assessment because of a history of excessive menstrual bleeding. Those found on ultrasound examination to have submucous fibroids who fulfil the inclusion criteria will be invited to join the study. Each woman will be randomised to either treatment or placebo group.

The treatment group will be 3.6 mg goserelin in a single dose syringe and the placebo group will be 5 ml of 1% lignocaine administered to the same site. All injections will be administered in the anterior abdominal wall every 28 days.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Goserelin

### Primary outcome measure
The success of hysteroscopic resection in achieving complete removal of fibroid.

### Secondary outcome measures
The length of the operation and associated complications in both treatment and placebo group.

### Overall study start date
01/10/2005

### Completion date
01/10/2006

## Eligibility

### Key inclusion criteria
1. Women with symptomatic submucous fibroids diagnosed on saline infusion hydrosonography
2. Fibroids suitable for hysteroscopic resection
3. Written informed consent obtained

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
120

### Key exclusion criteria
1. Fibroids not suitable for hysteroscopic resection
2. Written informed consent declined
3. Malignant histology discovered on histological analysis

### Date of first enrolment

01/10/2005

**Date of final enrolment**
01/10/2006

# Locations

**Countries of recruitment**
United Kingdom

**Study participating centre**
**King's College Hospital**
London
United Kingdom
SE 5 8RX

# Sponsor information

**Organisation**
King's College Hospital (UK)

**Sponsor details**
Denmark Hill
London
England
United Kingdom
SE5 8RX

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/01qz4yx77

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
King's College Hospital NHS Trust (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

## Study outputs

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