

# 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

☐ Prospectively registered

☐ Protocol

**Registration date**

30/11/2005

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

15/05/2012

**Condition category**

Urological and Genital Diseases

☐ 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

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

The success of hysteroscopic resection in achieving complete removal of fibroid.

**Key secondary outcome(s))**

The length of the operation and associated complications in both treatment and placebo group.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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)

## ROR

<https://ror.org/01qz4yx77>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

King's College Hospital NHS Trust (UK)

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/09/2010		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes