

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	<input type="checkbox"/> Prospectively registered
Registration date 30/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/05/2012	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Davor Jurkovic

Contact details

King's College Hospital
Denmark Hill
London
United Kingdom
SE 5 8RX

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