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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

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?
Results article	results	01/09/2010		Yes	No