ISRCTN10687405 https://doi.org/10.1186/ISRCTN10687405

Role of Intrauterine COrnual Block (ICOB) in combination with direct cervical block in outpatient endometrial ablation

Submission date
21/02/2013

Recruitment status
No longer recruiting

Registration date
07/11/2013

Overall study status
Completed

Last Edited
27/08/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are carrying out a study of 90 participants to find out whether giving a deeper local anaesthetic (numbing agent) inside the uterus in addition to the local anaesthetic routinely given to the neck of the womb (cervix) helps to control or reduce pain during the outpatient endometrial ablation procedure (removing the lining of the womb).

Who can participate?
Women, aged 18 - 50 years, coming to the gynaecology outpatient clinic for an outpatient endometrial ablation will be invited to participate in the study.

What does the study involve?
As part of the standard pain control method during an outpatient endometrial ablation, all women will receive an injection in the cervix of the uterus to freeze it. Patients are randomly allocated to one of two groups. The treatment group will receive an injection into the deep muscle containing only normal saline whereas the experiment group will receive fast/long-acting local anaesthesia (cornual block). Women will be asked to rate the degree of pain by placing a mark on a horizontal line. These scales will be given before the procedure, during the injection, immediately after, at one hour and at the time of discharge from the hospital.

What are the possible benefits and risks of participating?
There will be no immediate individual benefit to those taking part in the study, but there should be benefits to future patients undergoing a similar procedure to have much better pain relief and allow many more to have the procedure without the side effects of a general anaesthetic and its risks. In addition to having less pain, it is likely to reduce the number of painkillers needed as well as the length of stay in hospital. In future this may also allow a greater variety of procedures to be done in an outpatient setting with its benefits for many more patients. Some women may experience period-like pain when receiving the local anaesthetic but this normally settles within a few minutes, once the local anaesthetic becomes effective. In addition, some women may experience bruising of the wall of the uterus which usually resolves quickly. Although we use sterile (germ-free) instruments throughout there is a small risk of infection of

the uterus. All women will be asked to watch for any unusual symptoms such as a smelly vaginal discharge or fever and report back. Should an infection be suspected this will be managed with antibiotics.

Where is the study run from?
The study will be carried out in the outpatient hysteroscopy clinic at the Birmingham Womens Hospital, Birmingham, UK.

When is the study starting and how long is it expected to run for?
Recruitment started in February 2013. Participants will be enrolled on the study for a period of one year.

Who is funding the study?
The study will be funded by Ethicon, USA.

Who is the main contact?
Professor Janesh Gupta, j.k.gupta@bham.ac.uk
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01808898

Protocol serial number
12/BWH/NO75

Study information

Scientific Title

Randomized double-blind placebo controlled trial to assess the role of intrauterine cornual block (ICOB) in combination with direct cervical block in outpatient endometrial ablation

Acronym
ICOB

Study objectives
Outpatient local anaesthesic (LA) hysteroscopic intrauterine therapeutic interventions such as endometrial ablation have gained wider acceptance in the last decade. However, pain experienced during these procedures can be a disincentive and is the commonest reason for the use of escalating levels of analgesia post procedure, which results in prolongation of hospital stay and recovery. Various methods of LA have been studied including intrauterine topical lignocaine or cervical block using topical lignocaine, paracervical block or intracervical block. However, a single site block individually may not be sufficient to control the pain completely due to inability of the one site block to affect the sensitivity of the whole uterus, as the uterine fundus is effectively still unanaesthetised. This may be due to the uterus receiving complex innervations from different nerve routes such as the uterovaginal plexus, the Frankenhauser nerve plexuses, parasympathetic ganglia and the thoracic nerve.

Therefore, it seems logical to use a direct cervical block to block the sensation through uterovaginal plexus and use an additional deep myometrial block adjacent to each cornua to directly block the thoracic nerve supply. To date, only one small observational study has looked at the effect of such a combined block in relieving pain during outpatient hysteroscopic procedures. Therefore, we propose to undertake a double blind randomised controlled trial to address this question by comparing effectiveness of a standard direct cervical block and intrauterine cornual block (ICOB) versus a direct cervical block and a normal saline intrauterine cornual injection (control).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - South Birmingham, 22/01/13, REC Reference 12/WM/0411, IRAS Project ID 106381

Study design
Prospective double blind randomised placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Outpatient endometrial ablation

Interventions
Carried out in the outpatient one-stop hysteroscopy clinic at Birmingham Womens Hospital (BWH).

Active control: mepivacaine and bupivacaine (local anaesthetic). On the day of the procedure and before the patients are treated, a designated clinician will draw up the local anaesthetic (2 ml consisting of 1 ml of 3% mepivacaine (short/medium acting) and 1 ml of 0.5% bupivacaine

Placebo comparator: saline - normal saline solution (2 ml) in a 5 ml syringe

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
mepivacaine and bupivacaine

Primary outcome(s)
Visual Analogue Scale (VAS) evaluating pain administered before, during and immediately after to determine the effectiveness of intrauterine cornual block by evaluating pain directly attributable to outpatient hysteroscopic endometrial ablation assessed by using an ungraduated 10 cm VAS administered immediately after the procedure prior to patient going to the recovery unit.

Key secondary outcome(s))
1. VAS evaluating pain, 1 hour after procedure and at discharge from hospital to determine the effectiveness of intrauterine cornual block by evaluating pain using VAS at 1 hour after the procedure and prior to discharge from the hospital
2. To assess the total requirements for rescue analgesia in the first 24-hour post-operative period between the two groups

Completion date
31/07/2014

Eligibility

Key inclusion criteria
Women between the ages of 18 - 50 years presenting to the gynaecology outpatient clinic scheduled for an outpatient hysteroscopic intrauterine therapeutic intervention such as endometrial ablation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Women with contraindications to hysteroscopic procedures such as atypical endometrial hyperplasia or endometrial cancer, undiagnosed abnormal vaginal bleeding, current lower pelvic infection or uterine abnormalities
2. Women who are allergic to local anaesthesia
3. Not technically possible to perform a hysteroscopy e.g. women with distorted uterine cavity due to large fibroids
4. Women considered vulnerable (e.g. current mental illness, emotionally labile, or learning difficulties)
5. Women who decline to be randomised and request the additional anaesthetic or decline it will form a separate group to be studied and will be administered the VAS similar to the trial group. This group will be analysed separately to determine whether they are significantly different to those patients who consent to being part of the trial.

Date of first enrolment
01/02/2013

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
Mindelsohn Way
Edgbaston
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B15 2TG

Sponsor information

Organisation
Birmingham Women's Hospital (UK)

ROR
https://ror.org/00xe5zs60

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Current sources of funding as of 11/11/2013: Birmingham Womens Hospital, UK.

Funder Name
Previous source of funding: Ethicon (USA) - funding applied

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	01/02/2016	27/08/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes