**Intrauterine local anaesthetic after hysteroscopy to reduce post operative pain - A Randomised controlled trial**

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**Background**

Hysteroscopy is a common gynaecological procedure performed to assess women with abnormal uterine bleeding. It is normally performed as a day procedure under general anaesthesia. Pain after the procedure is usually minimal and many women are able to go home and resume normal activity the next day. However 20% of such women need additional analgesia while in the recovery ward and some require overnight hospital admission to control pain.

It is not standard practice to use additional local anaesthesia to reduce pain. Local anaesthesia for hysteroscopy can be administered by topical spray, by injection (intracervical or paracervical) or by squirting into the uterine cavity at the end of the procedure.

A literature of review of trials of intrauterine local anaesthetic administration has demonstrated inconsistent results (2). A systematic review and meta-analysis of randomized controlled trials demonstrated no significant effect of intrauterine anaesthetic (1). One RCT of 99 women with intrauterine local anaesthesia demonstrated no reduction in pain scores in those undergoing endometrial biopsy (3), and another using it for outpatient hysteroscopic sterilization also demonstrated no effect on the women’s pain score (4).

However, 2 other trials (5, 6) have demonstrated a beneficial effect. Another prospective RCT of 49 premenopausal women also demonstrated that topical intrauterine lignocaine plus misoprostol compared to misoprostol alone was effective in reducing the pain score of women undergoing hysteroscopy and endometrial biopsy (7). Addition of paracervical anaesthesia has also been shown to significantly reduce pain during hysteroscopy and biopsy (8).

The main reason for the inconsistent results appears to be related to the fact sample sizes in all the above studies was small and the systematic review concluded that more studies of sufficient size are required to address the problem. Any attempt to reduce pain and discomfort following the procedure would greatly improve women’s’ experience of the procedure.

**AIMS**

Main aim of the study is to assess the efficacy of a local anaesthetic solution inserted into the uterine cavity following hysteroscopy in reducing post operative pain.

**Primary hypothesis**

1. Intrauterine application of local anaesthetic has no effect on post operative pain as a result of hysteroscopy.

**Methodology**

**Study design**

This will be a prospective randomized double blind controlled trial

**Participants**

These will be women being booked for hysteroscopy and curettage with or without polypectomy, at Ipswich Hospital.

**Exclusion criteria**

Women with chronic pain

Known allergy to local anaesthetic

**Trial sites**

Ipswich Hospital

**Primary outcomes**

1. Pain score –on a score of 1-10 (1 being minimal and 10 being severe) at 2 hours and 24 hours post-operatively
2. Need for additional pain relief

Secondary outcome

1. Delay in return to normal activity

**Intervention group** – Women who are >50 kgs will have 10 mls of 0.75% (75mg) Chirocaine solution installed into the uterine cavity at the completion of the procedure

**Control group** – Women will have 10 mls of normal saline administered in the same manner.

**Randomisation**

Women will be seen at the Gynaecology clinic where a decision is usually made to perform hysteroscopy. At the time of consenting for the operation women will also be provided information regarding the study. After discussion demographic characteristics of the women consenting to participate will be recorded on the data sheet. This is purely to demonstrate that the two groups were comparable.

Randomisation will be using a computer generated equal numbered block of 10 random number tables. Allocation to treatment or control group will be by opening a sequentially numbered opaque sealed envelope available in theatre and opened towards the end of the procedure. The envelopes and randomization schedule will be prepared by a member of the research team not involved in the care of the woman.

**Patient safety**

Local anaesthetic agents such as Chirocaine are widely prescribed and used; for example in nerve blocks, wound repair and dental blocks. Like any drug they have potentially serious side effects if allergic or if injected intravascularly. They have a very good safety profile. Side effects are rare when used in the appropriate dose and in appropriate manner. The risks posed to the women participating would be no greater than any other drug application.

**Consent**

All women when being booked for a procedure will be provided with written information on the study. After discussion women will be requested for their written informed consent. The women will be assured that their participation is voluntary and that they may pull out of the study at any time.

**Study procedure**

The anaesthetic department will ensure that all women will have similar anaesthesia and analgesia intra and post operatively.

At the end of the procedure the anaesthetist will open the envelope containing the allocation. The anaesthetist will prepare the appropriate solution to be injected. Neither the surgeon, the patient nor any other theatre staff will be aware of the allocation.

Nursing staff in the recovery ward will as is the usual practice, check the pain scores at 2hrs post-op prior to women going home. The anaesthetists will have a standard template for post operative medications. These would be used in the recovery unit as required. At 2 hours post op the nurse will inquire and note down the severity of pain on a score of 1-10, a method that all nurses are familiar with.

The principal investigator will make a phone call on day 3 post-operative to assess use of additional pain relief and on return to normal activity. A chart review will be performed to collate the information on additional oral/IV analgesia used and number of women admitted overnight for pain relief.

**Confidentiality and data security**

Only members of the research team will have access to trial information. All information related to the trial will be kept locked in a filing cabinet kept in the principle investigator’s office

**Sample size**

Assume that the current incidence of need for additional post-operative analgesia is 20%.For a reduction to 10% with 80 % power and an alpha error of 0.05 we would need 219 women in each group. To allow for attrition we will have a sample size of 225 in each group.

**Research Ethics**

 The proposal will be submitted to the WMDDHS Research and Ethics Committee for approval.

**References**

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