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Study looking at which local anaesthetic method (KAPT or paracervical) provides better pain relief for women attending the hysteroscopy clinic

Submission date
01/09/2024

Recruitment status
No longer recruiting

Registration date
05/09/2024

Overall study status
Completed

Last Edited
05/09/2024

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A hysteroscopy is a test to look inside a woman's womb using a thin tube with a small camera inside it. This study aims to evaluate and compare the pain scores of women undergoing outpatient hysteroscopy when administered either the KAPT block or paracervical block, with an emphasis on understanding the relative effectiveness of these two anaesthetic techniques at critical stages of the outpatient hysteroscopy procedure: during cervical dilatation, throughout the procedure, and 10 minutes after the procedure.

Who can participate?
Patients aged 18 years and over attending outpatient hysteroscopy,

What does the study involve?
Participants are randomly divided into two equal groups. One group will have a paracervical block and the other group will have a KAPT block. A questionnaire will be handed over during and after the procedure to assess pain and determine the effectiveness of each anaesthetic technique.

What are the possible benefits and risks of participating?
There are no additional risks associated with taking part in the study. However, there are some minor side effects of the procedures and these will be covered in the procedure consent process. For example, patients may experience a sharp scratch during administration of the local anaesthetic due to the injection needle. Some patients may experience some side effects of the local anaesthetic including tingling sensation, headaches, dizziness and visual disturbances. These are very rare and temporary and usually wear off within a few minutes.

Where is the study run from?
Sherwood Forest Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2023 to August 2024

Who is funding the study?
Sherwood Forest Hospitals NHS Foundation Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
339976

Protocol serial number
REC 24/EM/0036

Study information

Scientific Title
Comparative analysis of pain relief between KAPT block and paracervical block for outpatient hysteroscopy procedures at Kings Mill Hospital: the KAPT-PARA block trial

Acronym
KAPT-PARA block

Study objectives
To determine which method, KAPT block or paracervical block, offers superior pain relief at critical stages of the outpatient hysteroscopy procedure: during cervical dilatation, throughout the procedure, and 10 minutes post-procedure. This will involve a detailed analysis of pain scores at these specific time intervals.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/06/2024, Health Research Authority (HRA), Health and Care Research Wales (HCRW) (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048115; approvals@hra.nhs.uk), ref: IRAS 339976, REC 24/EM/0036

Study design
Single-centre interventional single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Outpatient hysteroscopy procedures

Interventions
Paracervical Block for Outpatient Hysteroscopy Procedures is based on two key anaesthesia techniques:
1. KAPT Block: A sophisticated block targeting the Lee-Frankenhauser plexus, KAPT Block is effective in denervating the cervix and fundus. Its efficacy, demonstrated through observational studies, shows promising pain relief outcomes in outpatient hysteroscopy.
2. Paracervical Block (PCB): A commonly used technique in outpatient hysteroscopy, PCB's effectiveness is supported by a meta-analysis showing significant pain reduction. Although its superiority is debated, it remains a preferred method for pain control in these procedures.
The study aims to compare effectiveness in pain management for outpatient hysteroscopy, thus addressing the gaps in current understanding and practice.

Paracervical Block Technique:
The primary technique involves injecting 10ml of Citanest into the cervical stroma at the cervicovaginal junction. This can be done in two ways:
Four-point injection at 2, 4, 8, and 10 o'clock positions.
Two-point injection at 4 and 8 o'clock positions only.

KAPT Block Technique: 10 ml of Citanest
1. Inject 0.2 ml of Citanest directly into the cervical stroma at 6 and 12 o'clock to facilitate grasping with a tenaculum.
2. Measure 3 cm inferolateral from the external os towards 5 and 7 o'clock on both sides using a Pipelle sampler to locate the Lee-Frankenhauser plexus in the Uterosacral Ligament Complex (USLC).
3. Perform an inject-withdrawal technique, injecting a total of 4 ml at the measured sites on each side, distributed as follows:
3.1. 2 ml directly (Anterior to Posterior) at 5 o'clock and 7 o'clock. Sideways elevation of the lower lip of the cervix with a tenaculum can facilitate this step.
3.2. 2 ml from the medial to the lateral aspect at 5 o'clock and 7 o'clock, angling the syringe slightly for ease.
3.3. The depth of injection should be 25 mm, approximately ¾ of the length of the dental

syringe needle.
4. The objective is to infiltrate the LF plexus in both the supero-inferior and lateral planes.
5. Allow a pause of at least 3 minutes before commencing the procedure.

Research Question/Aim(s):
How do the pain relief outcomes of the King's Mill Anterior-Posterior and Transverse (KAPT) Block compare to the Paracervical Block in women undergoing outpatient hysteroscopy procedures

Objectives
1. To conduct a randomised control trial evaluating and comparing the pain scores of women undergoing outpatient hysteroscopy when administered either the KAPT Block or the Paracervical Block.
2. To determine which method, KAPT Block or Paracervical Block, offers superior pain relief at critical stages of the outpatient hysteroscopy procedure: during cervical dilatation, throughout the procedure, and 10 minutes post-procedure, through detailed analysis of pain scores at these specific intervals.
The outpatient hysteroscopy procedures will include:
Myosure removal of polyps
Myosure removal of fibroids
Thermablate endometrial ablation

This study will be a randomized control trial, comparing the efficacy of KAPT Block and Paracervical Block in outpatient hysteroscopy. This approach will provide robust, comparative data on the effectiveness of these anaesthetic techniques.

Data Collection Methods:
Patient Questionnaires with Visual Pain Score: Patients will complete questionnaires with a visual analogue scale (VAS) 0 to 10 score to self-report their pain levels at various stages of the procedure (during cervical dilatation, the procedure itself, and 10 minutes post-procedure). This method allows for direct, objective assessment of pain from the patient's perspective.

Data Analysis Methods:
Quantitative Analysis: The collected pain scores will be statistically analysed to determine the effectiveness of each anaesthetic technique. This analysis will involve comparing mean pain scores and assessing variations in pain experiences among patients.

Data Management:
Data will be de-identified to maintain patient confidentiality.
Electronic data will be securely stored and encrypted. Only authorized personnel will have access.
Hard copies, if any, will be kept in a secure location.
After the study, data will be archived as per institutional and legal guidelines.
Software: Statistical software will be used for quantitative data analysis.

Patient Public Involvement (PPI)
PPI groups have been involved with the study proposal process. A number of patients were asked specific questions regarding the study design and purpose. All information has been stored for future reference and publication.

A total of 10 patients were approached to complete a short questionnaire. The answers to the questionnaire concluded that 100 percent of patients agreed that the study would be beneficial

and is an important subject. The vast majority of patients stated they would participate in the study and the information provided is clear and concise.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain measured using the visual analogue score (VAS), during the procedure and 10 minutes after completion of the procedure

Key secondary outcome(s))
Patient comfort and tolerability will be assessed by asking patients after each method by answering YES or NO in a questionnaire format if they will recommend it to others and if they were satisfied with the pain relief method provided

Completion date
12/08/2024

Eligibility

Key inclusion criteria
1. Women attending outpatient hysteroscopy procedures at Kings Mill Hospital
2. Age 18 years and above
3. Willing to participate and able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Total final enrolment
48

Key exclusion criteria
1. Women with known contraindications to local anaesthetics
2. Women with a history of allergic reactions to the anaesthetics used

Date of first enrolment
25/06/2024

Date of final enrolment
12/08/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
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Sponsor information

Organisation
Sherwood Forest Hospitals NHS Foundation Trust

ROR
https://ror.org/04ce87537

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sherwood Forest Hospitals NHS Foundation Trust

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and /or analysed during the current study will be stored in a publicly available repository

IPD sharing plan summary

Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	16/04/2024	05/09/2024	No	No