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A double blind randomised placebo-controlled trial to compare the effectiveness of paracervical block plus Intrauterine anesthesia and paracervical block alone for pain relief during fractional durettage

Submission date 08/05/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/07/2005	**Overall study status** Completed	
Last Edited 10/09/2009	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
IUA

Study objectives
Compared with paracervical block alone, intrauterine anesthesia plus paracervical block would reduce maximum pain during fractional curettage for at least 2 cm, as measured by a 10-cm visual analogue score

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Local anesthesia for fractional curettage

Interventions
Intrauterine lidocaine plus paracervical block (experimental group) compared with intrauterine saline plus paracervical block (control group)

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
The reduction of a maximum pain score during fractional curettage.

Secondary outcome measures
Secondary outcomes included pain profile during fractional curettage, number of patients with pain score >4 cm, patients global satisfaction, types and incidence of adverse events, and serum lidocaine profile.

Overall study start date
01/04/2003

Completion date
31/10/2003

Eligibility

Key inclusion criteria
Women with abnormal uterine bleeding scheduled for fractional curettage.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
70

Key exclusion criteria
Patients who had the American Society of Anesthesiologists (ASA) physical status >II, genital organ infection, profuse uterine bleeding, a history of lidocaine hypersensitivity, a history of impaired liver function, were virgin, pregnant, or unable to understand how to score a 10-cm visual analogue scale (VAS) pain score.

Date of first enrolment
01/04/2003

Date of final enrolment
31/10/2003

Locations

Countries of recruitment

Thailand

Study participating centre
Department of Obstetrics and Gynecology
Bangkok
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10700

Sponsor information

Organisation
Mahidol University - Siriraj Grant for Research Development (Thailand)

Sponsor details
Faculty of Medicine
Siriraj Hospital
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10700

Sponsor type
University/education

ROR
https://ror.org/01znkr924

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Siriraj Grant for Research Development, Faculty of Medicine, Siriraj Hospital (Thailand)

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	01/09/2005		Yes	No