

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 durrettage

Submission date 08/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/07/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/09/2009	Condition category Surgery	<input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

The reduction of a maximum pain score during fractional curettage.

Key secondary outcome(s)

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.

Completion date

31/10/2003

Eligibility

Key inclusion criteria

Women with abnormal uterine bleeding scheduled for fractional curettage.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

Thailand

10700

Sponsor information**Organisation**

Mahidol University - Siriraj Grant for Research Development (Thailand)

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

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