Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Effectiveness of Spinal Anesthesia with Total Intravenous Anesthesia during Operative Hysteroscopy

Protocol summary

Summary

Hysteroscopy has become a widely accepted technique in the diagnosis and treatment of various gynecological conditions. Various types of anesthesia have been reported for diagnostic and operative hysteroscopic procedures. There are no controlled studies comparing different techniques of anesthesia. The aim of this study is to compare spinal versus general anesthesia regarding to per-operative outcomes in patients undergoing operative hysteroscopy. In a prospective comparative study, 76 ASA class I or II women aged 20-70 years are randomly assigned to undergo operative hysteroscopy with either spinal or total intravenous anesthesia. Inclusion criteria are patient aged 20-70 years; ASA class I or II; operative hysteroscopy; immediately after menstruation and exclusion criteria are contraindication for neuraxial block; allergy to local anesthetics; systemic disorders(cardiac, respiratory, hepatic, ...); psychosomatic disease; diagnostic hysteroscopy; large fibroid (uterine size> 12 w),and uterine prolapses. Outcomes are being the mean amount of irrigation fluid absorbed, postoperative serum sodium levels, incidence of hyponatremia, and level of patient's. satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402187013N11**
Registration date: **2014-06-06, 1393/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-06, 1393/03/16

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-05-24, 1393/03/03

Expected recruitment end date

2015-01-22, 1393/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effectiveness of Spinal Anesthesia with Total Intravenous Anesthesia during Operative Hysteroscopy

Public title

Comparison of Effectiveness of Spinal Anesthesia with General Anesthesia during Operative Hysteroscopy

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: patient aged 20-70 years; ASA class I or II; operative hysteroscopy; immediately after menstruation. Exclusion criteria: contraindication for

neuraxial block; allergy to local anesthetics; systemic disorders(cardiac, respiratory, hepatic, ...); psychosomatic disease; diagnostic hysteroscopy; large fibroid (uterine size> 12 w),and uterine prolapses.

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Vice chancellor for research, Tabriz University of Medical Sceinces, Daneshgah Square, Tabriz

City

Tabriz

Postal code

Approval date

2014-05-05, 1393/02/15

Ethics committee reference number

9321

Health conditions studied

1

Description of health condition studied

External causes of morbidity and mortality

ICD-10 code

Y85-Y89

ICD-10 code description

Sequelae of external causes of morbidity and mortality

Primary outcomes

1

Description

mount of irrigation fluid absorbed

Timepoint

End of operation

Method of measurement

ml

2

Description

patient's satisfaction scoring

Timepoint

During 24h after operation

Method of measurement

A four-point scale(weak, moderate, good, and excelent)

Secondary outcomes

1

Description

Serum sodium levels

Timepoint

End of operation

Method of measurement

mEq/l

Intervention groups

1

Description

In the control group (n=38) patients undergoing total intravenous anesthesia with midazolam, remifentanil and propofol. Maintenance of anesthesia is being with infusion of remifentanyl and propofl during procedure.

Category

Treatment - Drugs

2

Description

In the study group (n=38) patients undergoing spinal anesthesia at patient in sitting position, l3-4 or l4-5 interspinous space with 25-G quinke needle, and lidocaine 50 mg and fentanyl 15 µg medications.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Dr. Simin Atashkhoyi

Street address
Alzahra Hospital, South ArteshStreet, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Rashidi
Street address
Vice chancellor for research, Daneshgah Street, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty