

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of Spinal Anesthesia vs. General Anesthesia on analgesia& postoperative quality of recovery after abdominal hysterectomy

Protocol summary

Summary

Postoperative pain is the most significant complaint of patients undergoing abdominal hysterectomy despite the use of multimodal pain strategies. Neuroaxial anesthesia has opioid sparing effects and may provide better postoperative recovery when compared with general anesthesia. Our main objective in this study is comparing the effects of neuroaxial and general anesthesia on postoperative quality of recovery after abdominal hysterectomy. The study is prospective randomized controlled clinical trial. 100 healthy females will be recruited and randomized to general anesthesia or neuroaxial anesthesia as their primary anesthesia regimen. The primary outcomes will be global quality of recovery 40 questionnaires (Q.O.R 40) at 24 and 48 hours after the surgical procedure. Our data include the following parameters: Hemodynamic changes, Postoperative pain score, nausea and vomiting. Our data will be analyzed using the Mann-Whitney U test, Fisher's exact test, and linear regression. A P value <0.05 will be considered statistically significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309306148N3**

Registration date: **2013-10-23, 1392/08/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-23, 1392/08/01

Registrant information

Name

Hakimeh Alreza Amiri

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research Babol University Of Medical Sciences

Expected recruitment start date

2013-09-01, 1392/06/10

Expected recruitment end date

2014-09-01, 1393/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Spinal Anesthesia vs. General Anesthesia on analgesia& postoperative quality of recovery after abdominal hysterectomy

Public title

comparing the effects of neuroaxial and general anesthesia on postoperative quality of recovery after abdominal hysterectomy.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: ASA physical status I and II females undergoing total abdominal hysterectomy for benign (noncancerous) disease. Exclusion criteria: Patients with a history of coagulopathy; recent infection current; use of

an opioid analgesic or corticosteroid; history of migraine headache; gross neurologic impairment; suspected difficult airway

Age

From **35 years** old to **70 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University Of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Approval date

2013-08-27, 1392/06/05

Ethics committee reference number

3012/30/پ/ز

Health conditions studied

1

Description of health condition studied

Post operative analgesia after total abdominal hysterectomy

ICD-10 code

Z90.710

ICD-10 code description

Acquired absence of uterus

Primary outcomes

1

Description

Analgesia

Timepoint

6, 24, 48 hour after surgery

Method of measurement

Visual analogues Scale

2

Description

Quality of recovery

Timepoint

24, 48 hour after surgery

Method of measurement

QOR-40 questionnaire

Secondary outcomes

1

Description

Heart Rate

Timepoint

Before induction, during surgery and after surgery

Method of measurement

ECG

2

Description

Blood Pressure

Timepoint

Before induction of anesthesia, during surgery and after surgery

Method of measurement

Non invasive BP Cuff

3

Description

Nausea & Vomiting

Timepoint

After Surgery

Method of measurement

Question & Observation

Intervention groups

1

Description

Intervention group: 17.5 mg 0.5% bupivacaine with fentanyl 25 microgram was injected into subarachnoid space.

Category

Treatment - Drugs

2

Description

Control group: General anesthesia was induced with 0.1 mg/kg morphine and fentanyl 1-2 micrograms/kg and propofol 2 mg/kg, and atracurium 0.5 mg/kg. Continue of anesthesia will be with isoflurane 1-1.5MAC and N2O: O2 50%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Ruhani Hospital

Full name of responsible person

Dr Hakimeh Alereza Amiri

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor Of Research Babol University Of Medical Sciences

Full name of responsible person

Dr Amrolah Mostafazadeh

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor Of Research Babol 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

Contact

Name of organization / entity

Babol University Of Medical Sciences

Full name of responsible person

Dr Hakimeh Alereza Amiri

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work**Street address**

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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