

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Sprotte and Quincke needles with respect to post dural puncture headache

Protocol summary

Summary

Headache is one of the side effects of spinal anesthesia that can be caused by leakage of CSF from tip of the needle. The other side effects are backache, nausea, vomiting, tinnitus, hypotension and bradycardia. Size of puncture can affect on leakage of CSF, so the type of needle can influence on severity of side effects. In this double blind randomized trial 162 ASA physical status I or II patients scheduled for lower limb or lower abdominal segment operation under spinal anesthesia will be chosen. Patients will be randomly divided in two equal groups. Spinal anesthesia will be performed by either a 24-gauge Sprotte needle or a 24-gauge Quincke needle in median method. We will monitor blood pressure and pulse rate of patients up to 30 minutes after anesthesia. Then, up to 24 hours after that, every 4 hours, we will check patient's symptoms and fill checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009292080N4**
Registration date: **2010-12-28, 1389/10/07**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-28, 1389/10/07

Registrant information

Name

Afsaneh Norouzi

Name of organization / entity

Arak University of Medical Sciences

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Iran (Islamic Republic of)

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+98 86 1313 7474

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-10-22, 1389/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sprotte and Quincke needles with respect to post dural puncture headache

Public title

Comparison of Sprotte and Quincke needles with respect to post dural puncture headache

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: age 16- 65, patients with major surgery of lower limb or lower abdominal segment under spinal anesthesia. Exclusion criteria: patients with chronic headache and drug induced headache.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **162**

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

Arak University of Medical Sciences

Street address

Sardasht

City

Arak

Postal code

Approval date

2010-02-08, 1388/11/19

Ethics committee reference number

88-70-2

Health conditions studied

1

Description of health condition studied

headache

ICD-10 code

G44.8

ICD-10 code description

Other specified headache syndromes

Primary outcomes

1

Description

headache

Timepoint

every 4 hours till 24 hours after surgery

Method of measurement

checklist and physical exam

Secondary outcomes

1

Description

tinnitus

Timepoint

every 4 hours till 24 hours after surgery

Method of measurement

checklist & physical exam

2

Description

hypotension

Timepoint

every 4 hours till 24 hours after surgery

Method of measurement

checklist & physical exam

3

Description

vertigo

Timepoint

every 4 hours till 24 hours after surgery

Method of measurement

checklist & physical exam

4

Description

nausea & vomiting

Timepoint

every 4 hours till 24 hours after surgery

Method of measurement

checklist & physical exam

5

Description

nuchal rigidity

Timepoint

every 4 hours till 24 hours after surgery

Method of measurement

checklist & physical exam

Intervention groups

1

Description

Sprotte spinal needle

Category

Treatment - Devices

2

Description

Quincke spinal needle

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Arak University of Medical Sciences
Full name of responsible person
Dr. Afsane Norouzi
Street address
Valie asr hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Changiz Ashtiyani
Street address
Alamol hoda street
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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

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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