Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 cause 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 effect on leakage of CSF, so the type of needle can influence on severity of side effects. In this double blind randomize 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 hour after that, every 4 hour, 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

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Name of organization / entity
Arak University of Medical Sciences
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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 & vomitting
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
City
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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
Name of organization / entity
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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