

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of local pressure effect on needle puncture pain severity in patients candidates for spinal anesthesia

Protocol summary

Study aim

The effect of local pressure on the pain intensity of needle during spinal anesthesia

Design

Clinical trial with control group, with parallel groups, single blind, randomized, phase 3 on 120 patients. Randomization is performed within blocks.

Settings and conduct

This study is performed in the educational hospitals of Hamadan University of Medical Sciences by professors and assistants who are aware of the amount of pressure and the type of study. All patients are candidates for spinal anesthesia. In the case group, a pressure of 5 kg is applied to the entry point of the needle and the spinal anesthesia needle is immediately passed through the pressed area through the skin. This pressure is not applied in the control group. After anesthesia of patients, pain intensity is questioned based on verbal scale. Finally, pain intensity is analyzed and compared in case and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidates for spinal anesthesia

Exclusion criteria: Anesthesia criteria more than 3; More than once try to do a spinal; History of spinal surgery

Intervention groups

In the intervention group: a pressure of about 5 kg is applied to spinal needle entry point in the spinal anesthesia just before the needle enters. In the control group: no pressure is applied to spinal needle entry point in the spinal anesthesia.

Main outcome variables

Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121219011822N7**

Registration date: **2021-09-13, 1400/06/22**

Registration timing: **retrospective**

Last update: **2021-09-13, 1400/06/22**

Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Behrooz Karkhanei

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0574

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karkhanei@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-11, 1400/04/20

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

2021-07-11, 1400/04/20

Actual recruitment end date

2021-09-11, 1400/06/20

Trial completion date

2021-09-11, 1400/06/20

Scientific title

Evaluation of local pressure effect on needle puncture pain severity in patients candidates for spinal anesthesia

Public title

The effect of local pressure on pain severity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients are candidates for spinal anesthesia

Exclusion criteria:

American Society of Anesthesiology Score < 4
More than once tried to do spinal anesthesia
History of spinal surgery

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **116**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly assigned to four blocks using Random Allocation Software. Blocking and allocation sequences for concealment will be performed by the non-involved researcher (Allocation Concealment). The sample allocation ratio will be Allocation 1:1 and will be divided into two groups of receiving pressure and control group (Assignment). Then based on blocks and allocation sequences pressure will be given to patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

Since the participants do not know whether applying pressure before spinal needling is a routine method or not, they are unaware of the intervention (pressure on the injection site) and think that this pressure is applied to everyone. On the other hand, all participants are only asked about the severity of the needle pain and are not aware of the pressure or lack of pressure.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shaheed Fahmideh Blvd.

City

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Province

Hamadan

Postal code

6517838678

Approval date

2021-07-10, 1400/04/19

Ethics committee reference number

IR.UMSHA.REC.1400.306

Health conditions studied

1

Description of health condition studied

Pain in spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain severity

Timepoint

Immediately after spinal anesthesia

Method of measurement

Verbal Rating Scale (VRS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In patients undergoing spinal anesthesia, with a finger a pressure about 5 kg is applied to the needle entry point just before spinal anesthesia for 15 seconds.

Category

Prevention

2

Description

Control group: In patients who are candidates for spinal anesthesia, spinal anesthesia is performed routinely without pressure and just after prep and drep.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Fateme Ghasemi

Street address

Fatemieh hospital, Pasdaran Ave.

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Behrouz Karkhanei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Hamedan University of Medical Sciences

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available