Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Email address
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 perform 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
Hamadan
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.

City
Hamadan

Province
Hamadan

Postal code
6517789971

Phone
+98 81 3834 0082

Fax
+98 81 3825 1288

Email
fatemieh@umsha.ac.ir

Web page address
http://fth.umsha.ac.ir/

2

Recruitment center

Name of recruitment center
Besat hospital

Full name of responsible person
Fateme Ghasemi

Street address
Besat hospital, Shahid Beheshti Boulevard

City
Hamadan

Province
Hamadan

Postal code
6514845411

Phone
+98 81 3264 0047

Fax
+98 81 3265 1515

Email
besat@umsha.ac.ir

Web page address
http://besat.umsha.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Saeed Bashirian

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

City
Hamadan

Province
Hamadan

Postal code
6517838736

Phone
+98 81 3838 0717

Fax
+98 81 3838 0130

Email
fanavari@umsha.ac.ir

Web page address
http://research.umsha.ac.ir/

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

Street address
Besat hospital, Shahid Beheshti Boulevard

City
Hamadan

Province
Hamadan

Postal code
6514845411

Phone
+98 81 3264 0047

Email
karkhanei@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences
Full name of responsible person
Behrouz Karkhanei
Position
Assosiate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Besat hospital, Shahid Beheshti Boulevard
City
Hamadan
Province
Hamadan
Postal code
6514845411
Phone
+98 81 3264 0047
Email
karkhanei@umsha.ac.ir

Person responsible for updating data

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
Street address
Besat hospital, Shahid Beheshti Boulevard
City
Hamadan
Province
Hamadan
Postal code
6514845411
Phone
+98 81 3264 0047
Email
karkhanei@umsha.ac.ir

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