Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of the Effect of Regional Scalp Block and Pin-Site Infiltration on Heart Rate and Blood Pressure in Skull Pinning in Posterior Cervical Fusion Surgery: randomized control trial

Protocol summary

Study aim

Determining the effect of cranial regional block and infiltration at the pin site on heart rate and blood pressure during cranial pinning in patients undergoing posterior neck fusion surgery

Design

Clinical trial with control group, with parallel groups, three-blind, randomized, on 102 patients. The randomization site is used for randomization. https://www.sealedenvelope.com/simple-randomiser/v1/lists

Settings and conduct

This study is a randomized clinical trial. The target population is candidates for elective posterior cervical fusion surgery who referred to Al-Zahra Hospital in 1402. We have three groups, in which in addition to general anesthesia, in one group, bupivacaine and dexamethasone are administered as local injections in the pin-site area, and in the other group, scalp block with the same drugs is performed in 4 areas, and the third group is only under general anesthesia. Patients and people involved in data collection and analysis are not aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for posterior cervical fusion surgery; Age 18 to 65 years; Completing the informed consent form; American Society of Anesthesiologists I, II Exclusion criteria: Previous incision and previous history of neck surgery; Allergy to local anesthetic; Drug or alcohol addiction

Intervention groups

In the first group or group R, a mixture of bupivacaine and dexamethasone is injected bilaterally in 4 areas equally. In the second group or group P, the same amount of bupivacaine and dexamethasone are injected bilaterally at the pinning site. The third group is only under general anesthesia.

Main outcome variables

Systolic blood pressure, diastolic blood pressure, heart rate, Saturation of Peripheral Oxygen, mean blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110528006617N8**
Registration date: **2023-10-29, 1402/08/07**
Registration timing: **prospective**

Last update: **2023-10-29, 1402/08/07**
Update count: **0**

Registration date

2023-10-29, 1402/08/07

Registrant information

Name

Mehrdad Masoudifar

Name of organization / entity

Esfahan University of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of the Effect of Regional Scalp Block and Pin-Site Infiltration on Heart Rate and Blood Pressure in Skull Pinning in Posterior Cervical Fusion Surgery: randomized control trial

Public title
The Effect of Regional Scalp Block and Pin-Site Infiltration on Heart Rate and Blood Pressure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate patients for posterior cervical fusion surgery Age 18 to 65 years Completing the informed consent form American Society of Anesthesiologists I, II
Exclusion criteria:
Previous incision and previous history of cervical surgery Allergy to local anesthetic Drug or alcohol addiction
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **102**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling in this research is done in two stages. In the first stage, samples will be entered continuously based on the criteria for entering the study. In the second stage, the samples are assigned to groups in the form of a random permutation block design of three groups with blocks of three. In this way, the letter A is for the regional Regional Scalp Block, group B is for the Pin-Site Infiltration, and the letter C is for the regional scalp block group. The control group is considered. Then, all substitution compounds will be extracted from the site below until the sample size reaches the quorum. https://www.sealedenvelope.com/simple-randomiser/v1/lists To avoid bias, this work will be done by someone other than the researcher.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, patients and people involved in data collection and analysis are not aware of the grouping. After obtaining informed consent from eligible patients, they are randomly placed in 3 groups R, P and control, and the patients do not know which group they are in. After general anesthesia, a skilled doctor injects the drug. In the first group, injection is done in 4 areas, in the second group, in two areas. In the third group, no injection is performed. The person collecting the data does not know which group the patient belongs to. The person responsible for analyzing the data does not know which group this data belongs to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research Faculty of Medicine-Isfahan University of Medical Sciences
Street address
Hezarjarib Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-08-14, 1402/05/23
Ethics committee reference number
IR.MUI.MED.REC.1402.181

Health conditions studied

1

Description of health condition studied
Posterior cervical fusion surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
Basic time, from the time of intubation to the time of pinning every 3 minutes and from the time of injection to the time of surgical incision every 3 minutes
Method of measurement
Non invasive blood pressure

2

Description
Diastolic blood pressure
Timepoint
Basic time, from the time of intubation to the time of pinning every 3 minutes and from the time of injection to the time of surgical incision every 3 minutes
Method of measurement
Non invasive blood pressure

3

Description
Heart rate
Timepoint
Basic time, from the time of intubation to the time of pinning every 3 minutes and from the time of injection to the time of surgical incision every 3 minutes
Method of measurement
electrocardiogram(ECG)

Secondary outcomes

1

Description
Mean blood pressure
Timepoint
Basic time, from the time of intubation to the time of pinning every 3 minutes and from the time of injection to the time of surgical incision every 3 minutes
Method of measurement
Non invasive blood pressure

2

Description
Saturation of Peripheral Oxygen (SPO2)
Timepoint
Basic time, from the time of intubation to the time of pinning every 3 minutes and from the time of injection to the time of surgical incision every 3 minutes
Method of measurement
pulse oximetry

Intervention groups

1

Description
First intervention group: Regional Scalp Block (RSB) In this group, with a 25-gauge needle, we inject a mixture of 0.5% bupivacaine 0.5% and 2cc dexamethasone (equivalent to 8mg) bilaterally in the 4 areas of the supra-trochlear, supra-orbital, zygomaticotemporal, and auricotemporal nerves with a 25-gauge needle.
Category
Treatment - Drugs

2

Description
Second intervention group: Pin-Site Infiltration (PSI) In this group, a mixture of 0.5% bupivacaine 0.5% and 2cc dexamethasone (equivalent to 8mg) is injected bilaterally at the pinning site with a 25 gauge needle.
Category
Treatment - Drugs

3

Description
Control group: They are only under general anesthesia. General anesthesia includes 1.5 to 2 mg/kg of propofol, 0.03 to 0.05 mcg/kg of fentanyl, and 0.5 mg/kg of atracurium.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Al Zahra Hospital
Full name of responsible person
Mehrdad Masoudifar
Street address
Soffeh Blvd, Isfahan, Isfahan Province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Research and Technology Vice-Chancellor; Building No. 4; Isfahan University of Medical Sciences and Health Care Services; Hezar Jarib St
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mehrdad Masoudifar
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
There is no further information
When the data will become available and for how long
There is no further information
To whom data/document is available
There is no further information
Under which criteria data/document could be used

There is no further information

From where data/document is obtainable

There is no further information

What processes are involved for a request to access data/document

There is no further information

Comments