Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the Success rate between two different techniques of Scalp block: Ultrasound guided against using Landmarks

Protocol summary

Study aim

Comparison of scalp nerve block success rate between two landmark and ultrasound guided methods

Design

The study is a randomized clinical trial with two parallel groups of landmark and ultrasound and double-blinded with 60 samples. Randomization will be done with the help of Sealed envelope 2022 software and generating random sequences in the form of variable blocks (2,4 and 6) and the person who records the results and the statistical analyzer will be blind to the groups. In the first group, nerves will be identified using landmarks, and in the second group, nerve localization will be done under ultrasound guidance. The success of each injection will be checked by another anesthesiologist who is blind to the patient group. In addition, any unwanted complications will be monitored and recorded up to 12 hours after the nerve block. Finally, the data will be analyzed by a statistical analyst who is unaware of the sample group and the results will be reported.

Settings and conduct

In Shohada Tajrish Hospital in Tehran, the success rate of scalp block with two different techniques will be compared in craniotomy patients randomly divided into two groups, the anesthesiologist who checks the success of block and the data analyzer will be blind to samples group.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients aged 18-70 who are candidates for elective craniotomy, no history of chronic disease .Exclusion criteria:lack of patients cooperation.

Intervention groups

Patients will be divided into two groups of 30 people (landmark group and ultrasound group). Both groups of patients will undergo scalp nerve block before induction of anesthesia. In the first group, the nerves identified using landmarks and in the second group, drug injection will be done under ultrasound guidance.

Main outcome variables

Block success,Amount of drug used,Occurrence of complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200628047936N2**
Registration date: **2023-12-10, 1402/09/19**
Registration timing: **prospective**

Last update: **2023-12-10, 1402/09/19**
Update count: **0**

Registration date

2023-12-10, 1402/09/19

Registrant information

Name

Arash Tafrishinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 4715

Email address

arashtafrishi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-18, 1402/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the Success rate between two different techniques of Scalp block: Ultrasound guided against using Landmarks

Public title
Comparison of two different Scalp block techniques

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
A patient who is a candidate for craniotomy surgery age between 18-70 No diabetes and neuropathy No drug addiction Consciousness and complete wakefulness Not having clinical symptoms of increased intracerebral pressure (nausea, headache, diplopia) No history of sensitivity to local anesthetic

Exclusion criteria:
Lack of proper cooperation in evaluating the success of the block The presence of infection or cellulitis in the target area of the block Lack of proper cooperation during block

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **12**
For a complete block of sensation in the scalp area, 6 known nerves on each side of the skull are subjected to local anesthetic injection, which includes a total of 12 injections and blocks per person.

Randomization (investigator's opinion)
Randomized

Randomization description
In order to create a random sequence, randomization will be done with the method of variable blocks . A random sequence of 60 samples will be created in blocks of 2, 4, and 6 using online web based software (www.sealdenvelope.com), and the samples will be assigned to ultrasound and landmark groups based on the sequence created by the software and the order of patients' enrolling to study. The number of samples allocated to groups in each block will be equal. (Sealed Envelope Ltd. 2022)

Blinding (investigator's opinion)
Double blinded

Blinding description
After dividing the patients into two groups and performing the block by the anesthesiologist, after ten minutes the success of the block will be evaluated by another researcher who is unaware of the patient's group. In addition, the statistical analyzer will be unaware of the group of patients.

Placebo
Not used

Assignment
Parallel

Other design features
In this study, 60 patients who are candidates for craniotomy and are eligible to enter the study will be randomly divided into two groups of 30 people. The first group will undergo a scalp block using landmarks and the second group will undergo an ultrasound-guided scalp block before induction of anesthesia. 10 minutes after the injection, the success of each nerve block will be evaluated and recorded in the designed questionnaire. In addition, any possible complications will be registered and finally the results will be subjected to statistical analysis and reported. The researcher who checks the Block success and statistical analyzer will be blind to the groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshty University of Medical Sciences

Street address
Shahid Beheshty University of Medical Sciences, Yaman st., Velenjak

City
Tehran

Province
Tehran

Postal code
1467664961

Approval date
2023-05-02, 1402/02/12

Ethics committee reference number
IR.SBMU.MSP.REC.1402.012

Health conditions studied

1

Description of health condition studied
scalp block for craniotomy for brain mass

ICD-10 code
R90.0

ICD-10 code description
Intracranial space-occupying lesion found on diagnostic imaging of central nervous system

Primary outcomes

1

Description
the success of block
Timepoint
10 minutes after performing block
Method of measurement
the evaluation of sensation in blocked area

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the ultrasound group, in order to perform sculp block ,the localization of the cranial nerves is performed by known methods under the guidance of the ultrasound .In this group, all the nerves related to the scalp block (12 nerves) will be identified by ultrasound and they will be injected with 0.5% ropivacaine (Molteni ,Italia) using a 29G needle under ultrasound guidance.
Category
Treatment - Other

2

Description
Control group: In this group, in order to perform sculp block, the localization of the cranial nerves is done according to the usual methods and using the anatomy of the skull and face. In this group, all the nerves related to the scalp block (12 nerves) will be injected with 0.5% ropivacaine (Molteni ,Italia) using a 29G size needle.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Tajrish Hospital
Full name of responsible person
Arash Tafrishinejad
Street address
Shahrdari Ave., Ghods Sq.
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8000
Email
shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Arash Tafrishinejad
Street address
Yaman st., Velenjak
City
Tehran
Province
Tehran
Postal code
1467664961
Phone
+98 21 23871
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
50
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Arash Tafrishinejad
Position
Assistant Profedssor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Shohada hospital, Shahrdari Ave., Ghods sq.
City
Tehran
Province
Tehran
Postal code

1989934148

Phone
+98 21 2274 1174

Email
shohada@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Arash Tafrishinejad

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Shohada hospital, Shahrdari Ave., Ghods Sq.

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2271 8000

Email
arashtafrishi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Arash Tafrishinejad

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Shohada hospital, Shahrdari Ave., Ghods Sq.

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2271 8000

Email
arashtafrishi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
For scientific purposes only

From where data/document is obtainable
arashtafrishi@gmail.com Arash Tafrishinejad

What processes are involved for a request to access data/document
Request by email and response within 2 weeks

Comments