Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effect of scalp block in controlling pain and opioid use during and after surgery under Analgesia Nociception Index (ANI) monitoring in patients with elective craniotomy

Protocol summary

Study aim

Evaluation of the effect of scalp block on pain control and the amount of drug use during and after surgery in patients with elective craniotomy

Design

This randomized clinical trial will be conducted in 1401 at Sinai Hospital. In this study, adult patients aged 18 to 65 years with ASA status I and II who are to undergo elective craniotomy will be evaluated. They will be randomly divided into two groups of 36 so that the first group will receive the scalp block (intervention) and the second group will not receive the scalp block as a control.

Settings and conduct

This study will be performed as a randomized clinical trial in patients undergoing craniotomy at Sina Hospital. Two ANI monitor probes will be in the right place. In the scalp block group, unilateral scalp block will be performed under sterile conditions with bupivacaine

Participants/Inclusion and exclusion criteria

Study population: patients candidates for craniotomy Inclusion criteria: 1) Patients between 18 and 70 years old, 2) Candidate patients for craniotomy surgery, 3) ASA grade I-II and 4) Consent to enter the study Exclusion criteria: 1) Patients with arrhythmia, 2) Patients taking beta-blockers, 3) Pregnant women, 4) Patients for whom preoperative or postoperative ANI monitoring was discontinued. 5) Patients who had pre-operative beta-blocker injections, 6) Dissatisfaction with inclusion in the study, and 7) Patient non-cooperation

Intervention groups

Patients will be randomly divided into two groups so that the first group will receive scalp block (intervention) and the second group will not receive scalp block as a control.

Main outcome variables

Hemodynamic parameters during induction, Intubation, fixation of headpins, skin incision, craniotomy, and while waking the patient as well as the amount of remifentanil received during these times will be recorded and compared between the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170805035510N8**
Registration date: **2022-01-22, 1400/11/02**
Registration timing: **prospective**

Last update: **2022-01-22, 1400/11/02**
Update count: **0**

Registration date

2022-01-22, 1400/11/02

Registrant information

Name

Pejman Pourfakhr

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-05, 1401/01/16

Expected recruitment end date

2022-07-07, 1401/04/16

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

Scientific title
Evaluation of the effect of scalp block in controlling pain and opioid use during and after surgery under Analgesia Nociception Index (ANI) monitoring in patients with elective craniotomy

Public title
Evaluation of the effect of scalp block in controlling pain and opioid use during and after surgery under Analgesia Nociception Index (ANI) monitoring in patients with elective craniotomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ASA class 1,2 Elective Craniotomy
Exclusion criteria:
previous craniotomy pregnancy Patients with arrhythmia Patients taking beta blockers Chronic drug use
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the website www.sealedenveipoe.com, quadruple blocks were generated for randomization. The number of generated blocks will be 20 (sample size 72). The website generates blocks randomly (taking into account the number of study groups In each block are equal to each other) then they are provided to the person as Excel output. The determination of entry to the study is done based on the blocks made in order. Do not know or control groups based on generated blocks.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences and Health services
Street address
Tehran University of Medical Sciences, Central Building, Ghods Ave., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2021-04-22, 1400/02/02
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1400.014

Health conditions studied

1

Description of health condition studied
craniotomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The effect of scalp block in controlling pain and drug intake during and after surgery
Timepoint
Every 20 min
Method of measurement
ANI (MetroDoloris)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One-sided scalp block will be performed under sterile conditions with bupivacaine 2mg / kg and diluted epinephrine 1: 200000. Pain intensity, prescribed opioid dose as well as hemodynamic parameters during induction (T0), during operation (T6) and painful stimulation times such as intubation (T1), fixation of head pins (T2), skin incision (T3), craniotomy (T4), opening Dora (T5) and closing the skin (T7) and while waking the patient (T8) will be recorded at these times.

Category
Treatment - Drugs

2

Description
Control group: Control group: Craniotomy patients undergoing general anesthesia undergo surgery according to the protocol of the intervention group without scalp block and the amount of drug use and pain are compared with the intervention group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Pejman Pourfakhr
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Sina hospital, Hasan abad Square.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Pejman Pourfakhr
Position
Associate professor
Latest degree
Specialist
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Web page address

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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Not applicable
Title and more details about the data/document
monitoring device
When the data will become available and for how long
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
Use of the data is subject to the permission of all beneficiaries of this trial
From where data/document is obtainable
Pejman Pourfakhr - Tehran, Imam Khomeini St., Sina Hospital, Anesthesia Department, Tel: 02163128
What processes are involved for a request to access data/document
At the request of the Vice Chancellor for Research, Department of Anesthesiology, Tehran University of Medical Sciences
Comments