

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 remifentanyl 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

AgeFrom **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.sealedenvelope.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

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Tehran University of Medical Sciences, Central Building, Ghods Ave., Keshavarz Blvd.

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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

Street address

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

Other areas of specialty/work**Street address**

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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