

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison between effects of intravenous infusion Ibuprofen vs Morphine - Paracetamol on Platelet function in patients under supratentorial brain lesions resection

Protocol summary

Study aim

The main purpose was to determine the effect on platelet function of intravenous injection of ibuprofen with morphine-paracetamol using PFA-100.

Design

A clinical trial with two groups of intravenous infusion Ibuprofen and Morphine - Paracetamol, with parallel groups, randomized based on simple randomization with <https://www.randomizer.org> site, single blind Phase 3 on 15 patients in each group (totally 30)

Settings and conduct

In this randomized clinical trial single blind study, patients who are candidates for elective craniotomy surgery in Imam Hossein Hospital (1400-1401) are divided into two groups of 15 people - group I (B) and II (M-P). In both groups, at the beginning of Dora ligation, a blood sample was sent to assess coagulation disorder using the PFA-100 test, and then in a group I (B) ibuprofen 400 mg over 30 and in group II (MP) morphine 0.05 mg. G / kg is injected in the form of blues + paracetamol 1000 mg in half an hour. One hour after the injection, blood samples from both groups are sent for PFA-100 testing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 30 (two groups of 15) patients who are candidates for elective craniotomy surgery more than 16 years, no history of illegal inventions, gastrointestinal, liver, heart, kidney, diabetes, etc. Exclusion criteria: Hematocrit less than 25% During surgery, reduce your body to less than 36%

Intervention groups

Intervention 1- In group I, after removal of the brain lesion (at the beginning of Dora closure), 400 mg of ibuprofen solution is infused intravenously within 30 minutes. Intervention 2 - In group II, after removal of the brain lesion (at the beginning of Dora closure), morphine 0.05 mg/kg intravenous blues with 1000 mg of

paracetamol is infused for 30 minutes.

Main outcome variables

Blood Platelet function - pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210506051200N1**

Registration date: **2021-06-06, 1400/03/16**

Registration timing: **prospective**

Last update: **2021-06-06, 1400/03/16**

Update count: **0**

Registration date

2021-06-06, 1400/03/16

Registrant information

Name

Sohrab Salimi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between effects of intravenous infusion Ibuprofen vs Morphine - Paracetamol on Platelet function in patients under supratentorial brain lesions resection

Public title

Comparison between effects of intravenous infusion Ibuprofen vs Morphine - Paracetamol on blood Platelet function

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All surgeries for supratentorial lesions No history of coagulation disorders No history of gastrointestinal disease No history of liver disease Discontinue drugs that cause coagulation disorders No history of heart disease No history of renal failure (creatinine clearance <70 mL / min, oliguria or dialysis within 28 days before surgery) No history of diabetes No history of asthma Absence of 2 or more of the following: Alanine aminotransferase > 165 U / L, aspartate transaminase >, 120 U / L Alkaline phosphatase > 345 U / L (three cases too normal) Inability to obtain the consent of the patient or companions No history of disorders due to hypersensitivity to ibuprofen, aspirin, nonsteroidal anti-inflammatory drugs, COX-2 inhibitors - Women in non-pregnancy status No long-term use of anticonvulsant drugs No dependence or tolerance on drugs Weight higher than 30 kg No gastrointestinal bleeding during the last 6 weeks Do not take warfarin, lithium or concomitant use of lasix and angiotensin converting enzyme inhibitors

Exclusion criteria:

Hematocrit less than 25% during surgery Reduction of body temperature to less than 36 ° C

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

-Randomization method: Simple randomization - Randomization unit: individual -Randomization tool: Randomization will be done using the site <https://www.randomizer.org> which using random numbers extracted by the software, patients will be given one of the two groups of intravenous infusion Ibuprofen and Morphine - Paracetamol .

Blinding (investigator's opinion)

Single blinded

Blinding description

Drugs for both groups will be prepared and coded by one of the researchers in the study. Who will be aware of the type of drug will be injected. Because the participants are unconscious during the injection, they are spontaneously blind, and therefore only the patient does not know the type of drug used.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The ethical committee of Shahid Beheshti Medical University

Street address

Shahid Beheshti University of Medical Sciences, Shahid Erabi St, Ebne Yaman St, Shahid Chamran Highway, Tehran, Iran

City

tehran

Province

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Postal code

1985717443

Approval date

2019-07-02, 1398/04/11

Ethics committee reference number

IR.SBMU.MSP.REC.1398.307

Health conditions studied**1****Description of health condition studied**

supratentorial brain lesions

ICD-10 code

D33.0

ICD-10 code description

Benign neoplasm of brain, supratentorial

Primary outcomes**1****Description**

Platelet function using Pfa-100(CBC, PT, PTT, Ca2+, Pfa-100, INR, Fibrinogen, serum osmolality, ABG)

Timepoint

Once the Dora closure begins, a blood sample is taken first to measure coagulation abnormality using the

PfA-100 test. Also, one hour after the injection is completed, blood samples are taken from both groups for the PfA-100 test.

Method of measurement

The PFA-100 system is a platelet function analyzer designed to measure primary platelet-dependent homeostasis. (Platelet Function Assay or Platelet Function Analyzer): PFA-100

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: infusion Ibuprofen. In group I, 400 mg of ibuprofen solution is infused intravenously over 30 minutes after removal of the brain lesion (at the beginning of Dora closure).

Category

Treatment - Drugs

2

Description

Intervention group: Morphine - Paracetamol. In group II, after removal of the brain lesion (at the beginning of Dora closure), morphine is infused 0.05 mg / kg intravenously with 1000 mg paracetamol for 30 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان امام حسین

Full name of responsible person

سهراب سلیمی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

afshin zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

sohrab salimi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable