Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Nov 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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Iran (Islamic Republic of)

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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 commite 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
Tehran
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