

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of general anesthesia with Propofol infusion on Headache attack severity and frequency in patients with migraine

Protocol summary

Study aim

Evaluation of the effect of propofol on headache attack severity and frequency in patients with migraine

Design

Patients candidate for In Vitro Fertilization surgery and history of migraine will be enrolled into the study after signing the consent form and their severity and frequency of headache will be recorded in a questionnaire. Sample size was 60 persons categorized into 1 group. clinical trial, no randomization, no control group.

Settings and conduct

Patients candidate for In Vitro Fertilization surgery referred to Taleghani Hospital with a history of migraine receive propofol infusion during general anesthesia. In this study no blinding was performed

Participants/Inclusion and exclusion criteria

Inclusion criteria All the female patient between 25 to 50 years old Candidate for IVF(In Vitro Fertilization) surgery History of migraine Exclusion criteria Allergy to egg

Intervention groups

Intervention group: All patient receive Propofol (B.BRUAN company) infusion 100mcg/kg/min during general anesthesia fo In Vitro Fertilization surgery .

Main outcome variables

The effect of propofol on the severity and frequency of migraine headache attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190131042569N3**

Registration date: **2020-02-16, 1398/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-16, 1398/11/27**

Update count: **0**

Registration date

2020-02-16, 1398/11/27

Registrant information

Name

Nima saeedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2641 8939

Email address

nimasaeedi@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of general anesthesia with Propofol infusion on Headache attack severity and frequency in patients with migraine

Public title

The effect of Propofol on Headache attack severity and frequency in patients with migraine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All the female patient between 25 to 50 years old
Candidate for IVF(In Vitro Fertilization) surgery History of migraine

Exclusion criteria:

Allergy to egg

Age

From **25 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Shahid Beheshti University of
Medical Sciences

Street address

Shahid Beheshti University of Medical Science, Arabi
Ave , Daneshjoo Blvd ,Velenjak , Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.SBMU.MSP.REC.1398.111

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Headache severity in patients with migraine

Timepoint

1 , 3 , 6 month after anesthesia

Method of measurement

Visual Analogue Scale

2

Description

Headache frequency in patients with migraine

Timepoint

1 , 3 , 6 month after anesthesia

Method of measurement

questionnaire(Incidence per month)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patient receive Propofol (B.BRUAN
company) infusion 100mcg/kg/min during general
anesthesia fo In Vitro Fertilization surgery .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Nima Saeedi

Street address

Shahid Araabi Ave , Yaman Ave, Shahid Chamran
Highway

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taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Department of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziayi

Street address

Third floor, School of Medicine , near the Taleghani Hospital , Evin , Shahid Chamran Highway

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mpd@sbm.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Department of 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

Nima Saeedi

Position

Anesthesia assistance

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Full name of responsible person

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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

Participant data (age, pain severity) are to be shared.

When the data will become available and for how long

1 year after publication

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Using data and analysis for use in academic research

From where data/document is obtainable

Send Email Dr.Nima Saeedi Email Address:
nimasaeedi7@yahoo.com

What processes are involved for a request to access data/document

Send request via Email and after 1 week will be replied.

Comments