Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effect of premedication with oral acetaminophen on the prevention of localized pain from intravenous injection of propofol as induction agent in patients under general anesthesia

Protocol summary

Study aim
Evaluation of the effect of premedication with oral acetaminophen on the prevention of localized pain from intravenous injection of propofol

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 150 patients. Six-block method was used for individual randomization.

Settings and conduct
For this study, the license of the medical school and the ethics committee of Tehran University of Medical Sciences will be obtained. Data will be collected from 150 patients in the operating room of Shariati Hospital. We have 2 intervention groups with 500 mg and 1000 mg acetaminophen, and a control group with placebo. Patients receive oral medication one hour before entering the operating room. After delivery of a quarter of the calculated dose of propofol, the patient is asked to rate his or her pain at the injection site using VNRS. Both the patient and the pain assessor, are not aware of the type of oral medication. The anesthesiology resident gives the medications to the patients and collects the data recorded by the pain assessor and, before statistical analysis, matches the data with the patients.

Participants/Inclusion and exclusion criteria
Age 18 to 60 years; Use of propofol for anesthesia; Absence of liver and kidney disease; Absence of chronic pain in the body; Ability to communicate effectively

Intervention groups
The Pb, P500, and P1000 groups receive the drug one hour before transfer to the operating room. Each patient receives 2 placebo tablets (group Pb), 1 placebo tablet and 1 paracetamol 500 mg tablet (group P500) or 2 paracetamol 500 mg tablets (group P1000). Placebo and paracetamol are the same in shape, size, color and weight. None of them will receive painkillers or other sedatives.

Main outcome variables
The extent of local pain after intravenous injection of propofol

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210511051268N1**
Registration date: **2021-05-13, 1400/02/23**
Registration timing: **prospective**

Last update: **2021-05-13, 1400/02/23**
Update count: **0**

Registration date
2021-05-13, 1400/02/23

Registrant information

Name
Seyed Mohsen Mousavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8836 3149

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-09-21, 1400/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of premedication with oral acetaminophen on the prevention of localized pain from intravenous injection of propofol as induction agent in patients under general anesthesia

Public title
The effect of acetaminophen on propofol injection pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients for whom propofol is used as an induction of anesthesia
Exclusion criteria:
Weight less than 50 kg Chronic pain in any area of the body High blood pressure Cardiovascular disease Cerebrovascular disease Difficulty communicating (even if there is a marked drop in level of consciousness with the initial injection dose) Cirrhosis Abnormal liver function test results (AST and ALT more than twice normal) Kidney failure or creatinine clearance greater than 1.2 Allergy to acetaminophen Allergy to propofol Patients in whom propofol is not used to induce anesthesia Those who do not have a venous catheter in the back of the hand Those whose catheter size is not 20G those for whom we have to use rapid sequence induction for their anesthesia
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Restricted randomization is done using permuted block randomization method, with six blocks. Randomization was performed using the website www.randomization.com. The method of concealment is to use opaque envelopes sealed in random sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both the patient and an independent evaluator (in charge of anesthesia) and the researcher and data analyzer and the outcome evaluator are not aware of the type of oral medication. Placebo and paracetamol are the same in shape, size, color and weight.
Placebo
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
Street address
Enghelab St., Ghods St., Poursina St.
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2020-09-02, 1399/06/12
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.383

Health conditions studied

1

Description of health condition studied
Local Pain due to intravenous injection of propofol
ICD-10 code
M79.643
ICD-10 code description
Pain in unspecified hand

Primary outcomes

1

Description
11-point verbal numerical rating score (VNRS) for pain caused by propofol injection
Timepoint
Measuring the amount of pain right after injecting a quarter of the induction dose
Method of measurement
11-Point Verbal Numerical Ranking (VNRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: P500 group (patients with 500 mg of oral paracetamol) will receive medication 1 hour before transfer to the operating room. Each patient receives 1 placebo tablet and 1 paracetamol 500 mg tablet. (Because in the other intervention group, patients take 2 acetaminophen pills, so here they take one medicine pill and one placebo pill) None of them will receive any other analgesic or sedative. Aria 500 mg acetaminophen tablet is a product of Aria Pharmaceutical Company. Immediately after injecting a quarter of the propofol induction dose, the patient's local pain at the injection site is assessed by the VNRS numerical criterion and the patient scores from 0 to 10.

Category
Treatment - Drugs

2

Description
Control group: The placebo group receives the drug 1 hour before transfer to the operating room. Each patient receives 2 placebo tablets. (Because in one intervention group, patients take 2 acetaminophen pills, so here they take two placebo pills). None of them will receive any other analgesic or sedative. Immediately after injecting a quarter of the propofol induction dose, the patient's local pain at the injection site is assessed by the VNRS numerical criterion and the patient scores from 0 to 10.

Category
Placebo

3

Description
Intervention group: Intervention group: P1000 group (patients with 1000 mg of oral paracetamol) receive medication 1 hour before transfer to the operating room. Each patient receives 2 tablets of 500 mg paracetamol. None of them will receive any other analgesic or sedative. Aria 500 mg acetaminophen tablet is a product of Aria Pharmaceutical Company. Immediately after injecting a quarter of the propofol induction dose, the patient's local pain at the injection site is assessed by the VNRS numerical criterion and the patient scores from 0 to 10.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Operating room of Shariati Hospital in Tehran

Full name of responsible person
Alireza Saliminia

Street address
alal Al-Ahmad Highway, not far from Kargar, Shariati Hospital, first floor, operating room

City
Tehran

Province
Tehran

Postal code
1411713135

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Email
shariatihosp@tums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammad Ali Sahraeian

Street address
Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

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Phone
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Email
vcr@tums.ac.ir

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
Seyed Mohsen Mousavi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Tehran / Shahrak-e-Gharb / Dadman Blvd. / Sepehr St. / No. 117 / Unit 6
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
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
Access is free for everyone
Under which criteria data/document could be used
Access is free for everyone
From where data/document is obtainable
Person in charge of the project / Seyed Mohsen Mousavi sm.mousavi.md.anesthesiology@gmail.com
What processes are involved for a request to access data/document
Immediately after contacting the project manager
Comments