

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Evaluation of the effect of different doses of remifentanyl intranasal on hemodynamic changes induced by electroconvulsive therapy

#### Protocol summary

##### Study aim

Determination and comparison of the effect of different doses of remifentanyl intranasal on hemodynamic changes induced by electroconvulsive therapy

##### Design

Randomized, Controlled, Single-blinding clinical trial, with the parallel groups, Phase 3 on 80 patients

##### Settings and conduct

Eighty patients who are candidates for electroconvulsive therapy presented at Khorshid Hospital in Isfahan will be included and randomly divided into four groups. The 3 groups will receive 0.25, 0.50, and 0.75 mg/kg of remifentanyl respectively and the control group will receive a placebo. The specialist and the patient will not be aware of the type of intervention group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients aged over 18 years old; candidates for electroconvulsive therapy for the first time; classified as ASA I; no fever, and consent to participate in the study are included. Non inclusion criteria: allergy to remifentanyl; history of nasal diseases that interfere with the intranasal administration of the drug.

##### Intervention groups

Intervention group 1: Prior to electroconvulsive therapy, patients receive remifentanyl at a dose of 0.25 mg/kg intranasally in both nostrils. Intervention group 2: Prior to electroconvulsive therapy, patients receive remifentanyl at a dose of 0.5 mg/kg intranasally in both nostrils. Intervention group 3: Prior to electroconvulsive therapy, patients receive remifentanyl at a dose of 0.75 mg/kg intranasally in both nostrils. Control group: Prior to electroconvulsive therapy, patients receive a placebo intranasally in both nostrils. In all groups, 1 minute after the intervention, anesthetic induction drugs including midazolam, thiopental sodium, and succinylcholine were injected based on the patients' weight. Patients receive electroconvulsive therapy 30 to 45 seconds after receiving succinylcholine.

##### Main outcome variables

Blood pressure; Heart rate; Oxygen saturation; Duration of convulsion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200825048515N20**

Registration date: **2021-01-03, 1399/10/14**

Registration timing: **prospective**

Last update: **2021-01-03, 1399/10/14**

Update count: **0**

##### Registration date

2021-01-03, 1399/10/14

##### Registrant information

##### Name

Asieh Maghami Mehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 0000 0000

##### Email address

asimaghami@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-04, 1399/10/15

##### Expected recruitment end date

2021-05-21, 1400/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effect of different doses of remifentanyl intranasal on hemodynamic changes induced by electroconvulsive therapy

**Public title**  
The effect of remifentanyl intranasal on hemodynamic changes induced by electroconvulsive therapy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Aged over 18 years Candidates for electroconvulsive therapy for the first time Classified as ASA I based on American Society of Anesthesiologists Classification No fever Consent to participate in the study  
**Exclusion criteria:**  
Allergy to remifentanyl History of nasal-related diseases that interfere with intranasal drug administration

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
80 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In order to achieve the double-blind study, different doses of remifentanyl and placebo (without remifentanyl) will be prepared daily by the nurse of the electroshock ward (without the researcher's awareness) and placed in the bag and will be labeled A, B, C and D. And is given daily to the anesthesiologist (researcher). Therefore, the patient will not be aware of the type of medicine he/she is receiving.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8179964167

#### Approval date

2020-06-23, 1399/04/03

#### Ethics committee reference number

IR.MUI.MED.REC.1399.251

## Health conditions studied

### 1

#### Description of health condition studied

Electroshock therapy

#### ICD-10 code

Y84.3

#### ICD-10 code description

Shock therapy as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

## Primary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

1, 5, 10, and 20 minutes after the end of the convulsion

#### Method of measurement

Monitoring device

### 2

#### Description

Heart rate

#### Timepoint

1, 5, 10, and 20 minutes after the end of the convulsion

#### Method of measurement

Monitoring device

### 3

#### Description

Oxygen saturation

**Timepoint**  
1, 5, 10, and 20 minutes after the end of the convulsion

**Method of measurement**  
Monitoring device

#### 4

**Description**  
Duration of convulsion

**Timepoint**  
1, 5, 10, and 20 minutes after the end of the convulsion

**Method of measurement**  
Monitoring device

### Secondary outcomes

empty

### Intervention groups

#### 1

**Description**  
Intervention group 1: Prior to electroconvulsive therapy, patients receive remifentanyl at a dose of 0.25 mg/kg intranasally in both nostrils. One minute after the intervention, anesthetic induction drugs including midazolam, thiopental sodium, and succinylcholine are injected based on the patient's weight. Patients receive electroconvulsive therapy 30 to 45 seconds after receiving succinylcholine.

**Category**  
Treatment - Drugs

#### 2

**Description**  
Intervention group 2: Prior to electroconvulsive therapy, patients receive remifentanyl at a dose of 0.5 mg/kg intranasally in both nostrils. One minute after the intervention, anesthetic induction drugs including midazolam, thiopental sodium, and succinylcholine are injected based on the patient's weight. Patients receive electroconvulsive therapy 30 to 45 seconds after receiving succinylcholine.

**Category**  
Treatment - Drugs

#### 3

**Description**  
Intervention group 3: Prior to electroconvulsive therapy, patients receive remifentanyl at a dose of 0.75 mg/kg intranasally in both nostrils. One minute after the intervention, anesthetic induction drugs including midazolam, thiopental sodium, and succinylcholine are injected based on the patient's weight. Patients receive electroconvulsive therapy 30 to 45 seconds after receiving succinylcholine.

**Category**  
Treatment - Drugs

#### 4

**Description**  
Control group: Prior to electroconvulsive therapy, patients receive a placebo intranasally in both nostrils. One minute after the intervention, anesthetic induction drugs including midazolam, thiopental sodium, and succinylcholine are injected based on the patient's weight. Patients receive shock therapy 30 to 45 seconds after receiving succinylcholine.

**Category**  
Placebo

### Recruitment centers

#### 1

**Recruitment center**

**Name of recruitment center**  
Khorshid hospital

**Full name of responsible person**  
Behzad Nazemroaya

**Street address**  
Ostandari street.

**City**  
Isfahan

**Province**  
Isfahan

**Postal code**  
8145831451

**Phone**  
+98 31 3222 2127

**Email**  
behzad\_nazem@med.mui.ac.ir

### Sponsors / Funding sources

#### 1

**Sponsor**

**Name of organization / entity**  
Esfahan University of Medical Sciences

**Full name of responsible person**  
Shaghayegh Haghjoo Javanmard

**Street address**  
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

**City**  
Isfahan

**Province**  
Isfahan

**Postal code**  
8174673461

**Phone**  
+98 31 3668 8597

**Email**  
dean@med.mui.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
No

**Title of funding source**  
Isfahan 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

Jerib Street  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174675731  
**Phone**  
+98 31 3620 2020  
**Email**  
behzad\_nazem@med.mui.ac.ir

## Person responsible for updating data

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Behzad Nazemroaya  
**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Anesthesiology Department, Al-Zahra Hospital, Hezar  
Jerib Street  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174675731  
**Phone**  
+98 31 3620 2020  
**Email**  
behzad\_nazem@med.mui.ac.ir

**Contact**  
**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Shahram Sepyani  
**Position**  
Resident  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Anesthesiology Department, Al-Zahra Hospital, Hezar  
Jerib Street  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174675731  
**Phone**  
+98 31 3620 2020  
**Email**  
sepyani\_shahram@yahoo.com

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Behzad Nazemroaya  
**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Anesthesiology Department, Al-Zahra Hospital, Hezar

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no further information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available