Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim
Determination and comparison of the effect of different doses of remifentanil 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 remifentanil 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 remifentanil; history of nasal diseases that interfere with the intranasal administration of the drug.

Intervention groups
Intervention group 1: Prior to electroconvulsive therapy, patients receive remifentanil at a dose of 0.25 mg/kg intranasally in both nostrils. Intervention group 2: Prior to electroconvulsive therapy, patients receive remifentanil at a dose of 0.5 mg/kg intranasally in both nostrils Intervention group 3: Prior to electroconvulsive therapy, patients receive remifentanil 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)
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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 remifentanil intranasal on hemodynamic changes induced by electroconvulsive therapy

Public title

The effect of remifentanil 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 remifentanil 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 remifentanil and placebo (without remifentanil) 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

Isfehan

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 remifentanil 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 remifentanil 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 remifentanil 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

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Ostandari street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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

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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

Person responsible for general inquiries

Contact
Name of organization / entity
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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