Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Comparison of the effect of dexmedetomidine and remifentanil on analgesia and respiratory parameters in patients undergoing stereotactic brain biopsy

Protocol summary

Study aim

Comparison of the effect of dexmedetomidine and remifentanil on sedation analgesia and respiratory parameters in patients undergoing stereotactic biopsy

Design

The aim was to compare the efficacy of dexmedetomidine and remifentanil on sedation, hemodynamic changes, analgesia, respiration, and recovery during stereotactic brain biopsy. 40 patients are randomly divided into two groups based on admission criteria. Time to reach sedation scale (Ramsey 2–4), hemodynamic and respiratory changes, analgesia, and recovery from sedation are recorded.The person injecting and recording the information does not know the grouping of patients and the study is done as a blind.

Settings and conduct

Preoperative assessment, standard monitoring, G18 catheter, 2 liters of oxygen per minute, and the necessary equipment in difficult airways, the necessary tools for rapid opening of the form. Installation of stereotactic fram under local anesthesia of the scalp with 20 cc of 1.5% lidocaine and 50 mic /IV fentanyl and MRI. Group D: Intravenous dexmedetomidine 0.5 mic / kg loading dose: for 10 minutes and then 0.5 mic / kg / h by infusion pump Group R: Remifentanil, 1mic / kg IV bolus then 0.05 -0.2mic / kg / min IV by infusion pump With the aim of sedation with Ramssy 2-4. Recording of hemodynamic and unwanted complications during the procedure. Discontinue injection in case of Brady Penne (RR <8), Apnea> 15 seconds, SPO2 <94%.

Participants/Inclusion and exclusion criteria

Inclusion: 18-50 years old, normal liver and kidney , no drug addiction. Exclusion: comorbidities, brainstem lesions, intubated patients.

Intervention groups

Remifentanil (Mylan): 1mic/kg intravenous bolus and then 0.05 -0.2 mic/kg/ minute by infusion pump .

Dexmedetomidine (elixir): 0.5 mic/ kg/IV for 10 minutes and then 0.5 micr/kg/ hour by infusion pump

Main outcome variables

saturation . ,Seadation ,recovery,analgesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050983N2**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Sogol Asgari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8836 3185

Email address

drasgari98429@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of the effect of dexmedetomidine and remifentanil on analgesia and respiratory parameters in patients undergoing stereotactic brain biopsy

Public title

A Comparison of the effect of dexmedetomidine and remifentanil on analgesia and respiratory parameters in patients undergoing stereotactic brain biopsy

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18-50 years old candidate for stereotactic Patients with supratentorial lesions with or without hydrocephalus No dysfunction of the liver and kidneys No drug addiction Consent to participate in the study

Exclusion criteria:

BMI >35 or<16 mental disorder Uncontrolled epilepsy Alcohol and drug abuse Having a comorbid condition such as high blood pressure History of chronic pain Patients with brainstem lesions Intubated patients

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

En Permuted Randomized Blocks :In this method, 10 random blocks are generated by computer. Each block includes 5 people in the intervention group and 5 people in the control group. The order of these people is randomly arranged by computer and people are assigned to groups in the same way. At the end of each block, a new block of 10 is produced and this process will continue until the final sample volume is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

Forms with numbers 1 and 2 are used in packaged envelopes to group patients, which are given to patients randomly and patients do not know about the envelopes. After entering the envelope operating room by the anesthesiologist in charge of the patient Opened and according to the intervention group, the drug that was prepared in advance is given to the clinical caregiver for injection. The clinical caregiver is not aware of the grouping. The evaluator and recorder of the results and the person analyzing the data are also unaware of the grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice for Research and Technology, Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Yemen Street, Shahid Shahriari Square

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-12-01, 1400/09/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.657

Health conditions studied

1

Description of health condition studied

Stereotactic biopsy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hemodynamic parameters

Timepoint

Every 5 minutes from the moment you enter the operating room

Method of measurement

monitoring

2

Description

Respiratory parameters

Timepoint

Every 5 minutes from the moment you enter the operating room

Method of measurement

monitoring

3

Description

Seadation

Timepoint

Every 5 minutes from the moment you enter the operating room

Method of measurement

Ramssy Criteria

4

Description

Analgesia

Timepoint

Every 5 minutes from the moment you enter the operating room

Method of measurement

VAS criteria

5

Description

Recovery from sedation

Timepoint

Every 10 minutes after the procedure

Method of measurement

Aldert criteria

Secondary outcomes

empty

Intervention groups

1

Description

First, under local anesthesia of the scalp with 20 cc of 1.5% lidocaine and 50 micrograms of intravenous fentanyl, a stereotactic form is installed for the patient and the patient is transferred to radiology for MRI. Then 2 liters of oxygen per minute with a mask, 5 cc of normal saline per hour and 0.003 mg per kg of intravenous midazolam are given. Group D receive intravenous dexmedetomidine at the rate of 0.5 micrograms per kg per 10 minutes for 10 minutes. Then 0.5 micrograms per kilogram per hour is given by the infusion pump during the procedure.

Category

N/A

2

Description

First, under local anesthesia of the scalp with 20 cc of 1.5% lidocaine and 50 micrograms of intravenous fentanyl, a stereotactic form is installed for the patient and the patient is transferred to radiology for MRI. Then 2 liters of oxygen per minute with a mask, 5 cc of normal saline per hour and 0.003 mg per kg of intravenous midazolam are administered. Group R Remifentanil 1 microgram per kilogram of bolus and then 0.05 to 0.2 micrograms per kilogram. Receives grams per minute by infusion pump.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tajrish Shohada Hospital

Full name of responsible person

Faranak Behkaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Sogol Asgari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

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

En All data(questionnaire and the Excel file) can be shared after identifying individuals.

When the data will become available and for how long

Start access 6 months after printing results

To whom data/document is available

En Researchers working in academic institutions

Under which criteria data/document could be used

En If the study is conducted in a larger area between several hospitals

From where data/document is obtainable

En Email: drasgari98429@gmail.com Phone : 09127421711 Mrs. Dr. Sogol Asgari

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

En After identifying the people, the questionnaire and the Excel file will be sent via e-mail within a week.

Comments