

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of administration of Dexmedetomidine on recovery conditions in mentally-disabled adults, candidate for dental treatment under general anaesthesia

Protocol summary

Study aim

evaluating the effect of dexmedetomidine on recovery conditions in mentally-disabled adults undergoing dental treatment with general anesthesia

Design

This study is a randomized clinical trial, single blinded.

Settings and conduct

This is a single-blinded controlled clinical trial (assigning the first patient to the control or intervention group randomly and then the other patients are placed in a different group from the previous patient, respectively). This study will be carried out in Dental Hospital of Isfahan University of Medical Sciences. After anesthesia induction, patients in intervention group will receive 2 mcg/kg/hr Dexmedetomidine until the end of anesthesia. While under anesthesia, vital signs such as heart rate and blood pressure will be evaluated every 15 minutes. Anesthesia time will be recorded as the interval between administering and terminating anesthetics. Recovery time will be recorded as the interval between end of dental treatment and discharging the patient. Data collector, researcher and patients will be blinded.

Participants/Inclusion and exclusion criteria

inclusion criteria: mentally-disabled patients without systemic or physical disorders who need to undergo dental treatment under general anesthesia age range: 10-50 Patients unwilling to participate in the study or using tranquilizers, anticonvulsive, antidepressants, antipsychotic drugs or those allergic to soy or eggs, suffering from hepatic diseases or morbidly obese (BMI $\geq$ 40) will not be included.

Intervention groups

intervention group: Dexmedetomidine control group: Propofol

Main outcome variables

systolic blood pressure; heart rate; anesthesia time; needing analgesia in recovery; unrest in recovery;

recovery time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190626044013N2**

Registration date: **2021-04-16, 1400/01/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-16, 1400/01/27**

Update count: **0**

Registration date

2021-04-16, 1400/01/27

Registrant information

Name

Mahtab Tabesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5502

Email address

m-tabesh@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-10-07, 1400/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of administration of Dexmedetomidine on recovery conditions in mentally-disabled adults, candidate for dental treatment under general anaesthesia

Public title

Evaluation of Dexmedetomidine effect on mentally-disabled adults, candidate for dental treatment under general anaesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

mentally disabled without systemic diseases or physical disabilities need dental treatment under general anaesthesia

Exclusion criteria:

unwilling to participate in the study using tranquillizers, anticonvulsive, antidepressants, antipsychotic drugs allergic to soy or eggs hepatic diseases Morbidly obese (BMI≥40)

Age

From **10 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two categories of intervention and control. Class randomization: Patients fall into twenty-five standardized classes. There are two people in each class who are similar in age, sex and severity of the disease and are randomly assigned to one of the study groups. The allocation of people in each class is done randomly using envelopes in the package. For this purpose, each time, in two identical envelopes, the names of the participants and in two other identical envelopes, the names of the two study groups will be mentioned. Each envelope of participants will be randomly matched with an envelope of the study groups by lottery method without replacement, and then the envelopes are opened and each person is assigned to the relevant group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Although patients are informed about the study groups in detail prior to intervention, they are unaware of which group they are assigned to during the study. Also, the

outcome assessor is only aware of the code assigned to the patient and is not aware of the type of treatment received by him.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences- Ethics Committee

Street address

Isfahan University of Medical Sciences, Hezarjarib Avenue, Azadi Square

City

Isfahan

Province

Isfahan

Postal code

81174673461

Approval date

2020-09-06, 1399/06/16

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.763

Health conditions studied**1****Description of health condition studied**

mental disability

ICD-10 code

F79

ICD-10 code description

Unspecified intellectual disabilities

Primary outcomes**1****Description**

agitation in recovery

Timepoint

once

Method of measurement

Richmond Scale

Secondary outcomes

1

Description

heart rate

Timepoint

Once every 15 minutes during anesthesia

Method of measurement

pulsometer

2

Description

anesthesia time

Timepoint

Once during anesthesia

Method of measurement

clock

3

Description

analgesia need in recovery

Timepoint

Once during the patient's recovery

Method of measurement

recording

4

Description

recovery time

Timepoint

Once during the patient's recovery

Method of measurement

clock

5

Description

systolic blood pressure

Timepoint

Once every 15 minutes during anesthesia

Method of measurement

pressure cuff

Intervention groups

1

Description

Intervention group: 2 mcg/kg/hr dexmedetomidine will be administered via infusion until the end of general anesthesia

Category

Treatment - Drugs

2

Description

Control group: 50% N2O / 50% O2 along with 100 mcg/kg/min will be administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School Isfahan University of Medical Sciences

Full name of responsible person

Dr Naser Kaviani

Street address

Dental Hospital, Dental School of Isfahan University of Medical Sciences, Hezarjarib Avenue, Azadi Square,

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Email

kaviani@dnt.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Naser Kaviani

Street address

Isfahan University of Medical Sciences, Hezarjarib Avenue, Azadi Square,

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Email

research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Naser Kaviani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Dental Hospital, Dental School of Isfahan University of Medical Sciences, Hezarjarib Avenue, Azadi Square,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact

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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

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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data concerning main outcomes will be shared.

When the data will become available and for how long

6 months after publication

To whom data/document is available

Data will be available for academic researchers.

Under which criteria data/document could be used

in order to perform further analysis

From where data/document is obtainable

Requests should either be sent via email to kaviani@dnt.mui.ac.ir, or the person should refer to Dental School of Isfahan University of Medical Sciences.

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

A written request containing related information and affiliation(s) with the reason why these data are needed should be submitted.

Comments