

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The effect of dexmedetomidine and ketamine on core body temperature changes in children under sedation during MRI

Protocol summary

Study aim

The effect of dexmedetomidine and ketamine on changes in body temperature in children

Design

randomized, triple-blind trial on children aged 6 months to 10 years with ASA physical status class I-II, at Mofid Hospital during the year 1404 (2025). total of 60 patients will be randomly assigned into two groups using a sealed-envelope method: Group I (Dexmedetomidine group) Group II (Ketamine group). The data obtained will be analyzed using SPSS software, version 26.

Settings and conduct

This prospective, randomized, triple-blind study will be conducted on children aged 6 months to 10 years with ASA physical status I-II who undergo MRI under anesthesia at Mofid Hospital in the year 1404 (2025). Patients will be randomly allocated into two groups using sealed envelopes: Group I (Dexmedetomidine group) and Group II (Ketamine group). Bilateral tympanic membrane temperatures will be measured and recorded for both groups before entering the MRI unit by an anesthesiologist blinded to the group assignments. Data obtained from the study will be analyzed using SPSS software version 26.

Participants/Inclusion and exclusion criteria

children aged 6 months to 10 years with ASA physical status class I-II, who undergo MRI under general anesthesia at Mofid Hospital during the years 1404 (2025). Exclusion criteria will include allergy to intravenous anesthetics, severe cardiac or pulmonary disease, increased intracranial pressure or epilepsy, an initial body temperature of 37.5°C or higher, and signs of dehydration.

Intervention groups

Dexmedetomidine group Ketamine group

Main outcome variables

Determination of the effects of dexmedetomidine and ketamine on central body temperature in children based on age, sex, indication for MRI, baseline body

temperature, MRI duration, heart rate, oxygen saturation, body surface area, and imaging region.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250722066589N1**

Registration date: **2025-07-31, 1404/05/09**

Registration timing: **prospective**

Last update: **2025-07-31, 1404/05/09**

Update count: **0**

Registration date

2025-07-31, 1404/05/09

Registrant information

Name

Malihe Abniki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 25719

Email address

dr.abniki@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2025-10-23, 1404/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dexmedetomidine and ketamine on core body temperature changes in children under sedation during MRI

Public title

The effect of dexmedetomidine and ketamine on core body temperature changes in children under sedation during MRI

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Children aged 6 months to 10 years with ASA class I-II undergoing MRI under anesthesia at Mofid Hospital in the year 1404 (2025)

Exclusion criteria:

Allergy to intravenous anesthetics severe cardiac disease severe pulmonary disease increased intracranial pressure epilepsy initial body temperature of 37.5°C or higher signs of dehydration in the patient

Age

From **6 months** old to **10 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to two groups using a sealed envelope method: Group I (Dexmedetomidine group) and Group II (Ketamine group).

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients will be assigned to two groups using a sealed envelope method: Group I (Dexmedetomidine group) and Group II (Ketamine group). Upon enrollment, the envelope will be opened to determine the allocated drug, without the care provider being aware of the drug identity. Based on this allocation, the care provider will administer the medication, and patient data will be collected accordingly. In addition to the patient and the care provider, the data analyst will also be blinded to the type of intervention to ensure unbiased analysis of the results

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Building No. 2 , Fifth Floor, Shahid Arabi Street , Yemen Street, Shahid Chamran Highway, Tehran -

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2025-07-21, 1404/04/30

Ethics committee reference number

IR.SBMU.RETECH.REC.1404.214

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

The effect of dexmedetomidine and ketamine on core body temperature changes in children under sedation during MRI

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The effect of dexmedetomidine and ketamine on body temperature changes in children under anesthesia during MRI imaging based on demographic variables.

Timepoint

Before and after MRI

Method of measurement

Thermometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dexmedetomidine

Category

Prevention

2

Description

Control group: ketamine

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mophid Hospital

Full name of responsible person

Malihe Abniki

Street address

Mophid Hospital , shariati street , Tehran Town

City

Tehran

Province

Tehran

Postal code

1551415468

Phone

+98 21 2222 7021

Email

info-mch@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice-Chancellor for Research and Technology at
Shahid Beheshti University of Medical Sciences

Street address

Negative One Floor, Bookstore Building ,Shahid
Beheshti University , Erabi Ave, Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717434

Phone

+98 21 2243 9951

Email

mpd@sbmu.ac.ir

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

Malihe Abniki

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Department of Anesthesiology , 4th Floor , shohada-y-
tajrish Hospital Valiasr street

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2271 8000

Email

dr.abniki@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Malihe Abniki

Position

Assistant Professor

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Fax
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dr.abniki@sbmu.ac.ir

Fax
Email
dr.abniki@sbmu.ac.ir

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

Data collection and analysis are fully shareable.

When the data will become available and for how long

Since data collection began in September 1404

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Changes to data are not allowed

From where data/document is obtainable

Dr Malihe Abniki

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

3 -6 mon

Comments

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Malihe Abniki
Position
Assistant Professor
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Other areas of specialty/work
Anesthesiology
Street address
Department of Anesthesiology , 4th Floor , shohada-y-tajrish Hospital Valiasr street
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Province
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Postal code
1989934148
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+98 21 25719