Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 21 25719

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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
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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
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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
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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
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