

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of oral melatonin in reduction pain during venipuncture _a double blind clinical trial

Protocol summary

Study aim

The effect of oral melatonin in reduction pain during venipuncture in children referred to Taleghani Children's Hospit

Design

The study will be conducted on children aged 3 to 6 who will be referred to the hospital for whom venipuncture will be performed. The children will be randomly divided into two groups A (melatonin receivers) and B group (placebo receivers). The study is double blind.

Settings and conduct

The study will be conducted in Taleghani Hospital, Gorgan, on children aged 3 to 6 who will undergo vein extraction. The children will be randomly divided into two groups: A (melatonin recipient) and B group (placebo recipient). The study is double blind

Participants/Inclusion and exclusion criteria

inclusion criteria : children with 3-6 y old referred to Taleghani hospital need to venipuncture for intravenous infusion parental consent to participate in the study
exclusion criteria : loss of consciousness acut and lifethreatening state any psychological disorder (ADHD , autism) receive any sedative or pain releif drug emergency state

Intervention groups

melatonin recipient group

Main outcome variables

Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220812055665N1**

Registration date: **2022-11-28, 1401/09/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-28, 1401/09/07**

Update count: **0**

Registration date

2022-11-28, 1401/09/07

Registrant information

Name

Zohre Akbari jokar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral melatonin in reduction pain during venipuncture _a double blind clinical trial

Public title

The effect of oral melatonin in reduction pain during venipuncture _a double blind clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

children with 3-6 y referred to Taleghani Hospital Parental consent for the child to participate in the study need to venipuncture for intravenous infusion Exclusion criteria: loss of consciousness acute and life threatening state any psychological disorder (autism , ADHD) any reaction to melatonin use any sedative or pain relief drug emergency state	Used Assignment Parallel Other design features
Age From 3 years old to 6 years old	Secondary Ids empty
Gender Both	Ethics committees
Phase 3	1
Groups that have been masked • Participant • Care provider • Investigator	Ethics committee Name of ethics committee Ethics committee of Golestan University of medical science Street address Hirkan Blvd City Gorgan Province Golestan Postal code ۴۹۳۴۱۷۴۵۱۵
Sample size Target sample size: 202	Approval date 2022-10-16, 1401/07/24
Randomization (investigator's opinion) Randomized	Ethics committee reference number IR.GOUMS.REC.1401.351
Randomization description Randomization method and tool: In this study, we will use the restricted randomization method of the block randomization type. Blocking is usually used in order to create a balance in the number of samples allocated to each of the studied groups. This feature helps researchers to ensure that the number of samples allocated to each of the study groups is equal in cases where intermediate analyzes are needed during the sampling process. The total size of the blocks is equal and in this trial we will have two groups of 6 blocks including 3 participants in the intervention group and 3 participants in the control group. The randomization tool is also used from random allocation software, which, in addition to simple randomization, is capable of generating random sequences using the block method.	Health conditions studied
Blinding (investigator's opinion) Double blinded	1
Blinding description Concealment: We will use allocation concealment. By using opaque letter envelopes sealed with a random sequence, in this method, each of the generated random sequences is recorded on a card and the cards are placed inside the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed. Double masked blind Both patients and all researchers related to patients are unaware of the patient's perceived exposure. The patient can be identified with a code that is placed in an envelope, and in another place it is clear whether this number is a medicine or a placebo.	Description of health condition studied Pain during venipuncture ICD-10 code G89.18 ICD-10 code description Other acute postprocedural pain
Placebo	Primary outcomes
	1
	Description pain score is primary outcome.
	Timepoint 30 to 60 min after drug consumption
	Method of measurement FLACC score (measurement changes of face,legs,activity,cry,consolability)
	Secondary outcomes
	1
	Description secondary outcome is anxiety
	Timepoint 30-60 min after drug consumption

Method of measurement

observation

Category

N/A

2**Description**

success in venipuncture

Timepoint

30-60 min after drug consumption

Method of measurement

observation

3**Description**

child cooperation

Timepoint

30-60 min after drug consumption

Method of measurement

observation

Intervention groups**1****Description**

Intervention group: This group includes children to reduce pain and restlessness during venipuncture, melatonin drug will be used for them before venipuncture, and then the success of this method will be evaluated. This group includes 3 to 6 year old children receiving melatonin medication, who receive a single dose of 0.5 mg/kg and a maximum dose of 5 mg 30 to 60 minutes before venipuncture. The melatonin tablet is from jalinous company and has a dose of 5 mg, which is dissolved in 5 cc of water by a trained nurse before use and is given to the child with the mentioned dose. Older children can take the medicine in pill form. After 30 to 60 minutes, venipuncture will be done, and during venipuncture, the child's reactions will be evaluated based on the flacc criteria.

Category

N/A

2**Description**

Control group: This group includes children to reduce pain and restlessness during venipuncture, melatonin placebo will be used for them before venipuncture, and then the success of this method will be evaluated. This group includes children aged 3 to 6 years who receive a single dose of placebo with a dose of 0.5 mg/kg and a maximum dose of 5 mg 30 to 60 minutes before venipuncture. The melatonin placebo is from jalinuos company and is completely similar to the 5 mg melatonin tablet. The placebo is dissolved in 5 cc of water by a trained nurse and given to the child with the mentioned dose. Older children can take the medicine in the form of tablets with the correct dosage. After 30 to 60 minutes, venipuncture will be done, and during venipuncture, the child's reactions will be evaluated based on the flacc criteria.

Recruitment centers**1****Recruitment center****Name of recruitment center**

Taleghani hospital

Full name of responsible person

Zohre Akbari Jokar

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Mrs. Professor Narges Begum Mir Behbahani

Street address

Gorgan , janbazan Blvd , taleghani's hospital

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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

Gorgan 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**

Gorgan University of Medical Sciences

Full name of responsible person

Zohre Akbari jokar

Position

Pediatric resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

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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

preservation of personal information

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

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

No - There is not a plan to make this available

Title and more details about the data/document

Statistical Analysis Plan Study protocol Clinical trial report

When the data will become available and for how long

2 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

using data for a larger study using data for similar study

From where data/document is obtainableDr zohre akbari jokar Zohreakbari2351@yahoo.com
09104323922**What processes are involved for a request to access data/document**

The applicant should contact me via e-mail or mobile phone number and state his request and the reason for the need for information. After consulting with the research group and the Guide master, the information will be provided to them.

Comments

