Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 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 reffered 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 psycological 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)
Phone
+98 21 3623 9056
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zohreakbari2351@yahoo.com

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 reffered 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

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **202**

Randomization (investigator's opinion)
Randomized

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.

Blinding (investigator's opinion)
Double blinded

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.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

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

Approval date
2022-10-16, 1401/07/24

Ethics committee reference number
IR.GOUMS.REC.1401.351

Health conditions studied

1

Description of health condition studied
Pain during venipuncture

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

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

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.
Category
N/A

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
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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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Person responsible for updating data

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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 obtainable
Dr 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