Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of oral melatonin on urinary tract infection in children and adolescents

Protocol summary

Study aim
Determining the effect of melatonin on urinary tract infection in children and adolescent

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 100 patients. Randomized permutation block method was used for randomization.

Settings and conduct
100 patients with urinary tract infection and simultaneous sleep disorder referring to Amirkabir Arak Hospital were divided into two intervention groups (receiving 5 mg melatonin tablets daily for 10 days along with antibiotics) and control (antibiotics with placebo) in the form of block randomization. will be After explaining the purpose and steps of the study to the parents of the patients, a checklist is completed for each person, in which the child reports abdominal pain, burning and frequency of urination to the parents on the days under study, and their improvement is checked during the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children aged 4-18 with urinary tract infections and sleep disorders at the same time, consent to participate in the study; Inclusion criteria: The presence of underlying kidney disease

Intervention groups
In the control group, patients receive antibiotics and placebo for 10 days as a standard treatment for urinary infection. In the intervention group, in addition to antibiotics, patients will receive 5 mg melatonin tablets produced by Jalinous Iranian Pharmaceutical Company at a dose of 5 mg once a day for 10 days.

Main outcome variables
Fever above 38 degrees Celsius, Dysuria, frequency and its number of occurrences, abdominal pain, urinary incontinence, and its number of occurrences

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241125063843N1**
Registration date: **2025-01-08, 1403/10/19**
Registration timing: **retrospective**

Last update: **2025-01-08, 1403/10/19**
Update count: **0**

Registration date
2025-01-08, 1403/10/19

Registrant information

Name
Amirvali Azodzadeh ardakani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3238 2383

Email address
azodzadeh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-26, 1403/09/06

Expected recruitment end date
2024-12-26, 1403/10/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of oral melatonin on urinary tract infection in children and adolescents

Public title

Investigating the effect of oral melatonin on urinary tract infection in children and adolescents

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 4-18 with urinary tract infection and sleep disorder at the same time Consent to participate in the study

Exclusion criteria:

The presence of underlying kidney disease

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is done by a statistician with blocks of 6 along with the randomization code through the site sealedenvelope.com

Blinding (investigator's opinion)

Double blinded

Blinding description

To conduct this double-blind study, before starting the investigation, the total number of capsules for both the intervention and control groups, which are identical in shape, color, and appearance and obtained from the same pharmaceutical company, will be coded as A and B by a person other than the researcher to ensure that the researcher remains unaware of which type of capsules each group receives. Additionally, the participants, who are randomly assigned to groups A and B without knowledge of whether they are in the supplement or placebo group, will receive the capsules for a duration of 10 days.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences Headquarters., next to Amir Kabir Hospital., Alam El Hoda St., Shahid Shiroudi St.

City

Arak

Province

Markazi

Postal code

3848176591

Approval date

2024-11-10, 1403/08/20

Ethics committee reference number

IR.ARAKMU.REC.1403.254

Health conditions studied

1

Description of health condition studied

Urinary tract infection

ICD-10 code

N39.0

ICD-10 code description

Urinary tract infection, site not specified

Primary outcomes

1

Description

Fever

Timepoint

Within 10 days of starting antibiotic treatment and taking melatonin daily

Method of measurement

Thermometer

2

Description

dysuria

Timepoint

Within 10 days of starting antibiotic treatment and taking melatonin daily

Method of measurement

Patient statements

3

Description

Urinary frequency

Timepoint

Within 10 days of starting antibiotic treatment and taking melatonin daily

Method of measurement

Patient statements

4

Description
Abdominal pain
Timepoint
Within 10 days of starting antibiotic treatment and taking melatonin daily
Method of measurement
Patient statements

5

Description
Urinary incontinence
Timepoint
Within 10 days of starting antibiotic treatment and taking melatonin daily
Method of measurement
Patient statements

6

Description
The number of Urinary frequency
Timepoint
Within 10 days of starting antibiotic treatment and taking melatonin daily
Method of measurement
Patient statements

7

Description
The number of Urinary incontinence
Timepoint
Within 10 days of starting antibiotic treatment and taking melatonin daily
Method of measurement
Patient statements

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:In addition to receiving standard antibiotic treatment, patients will receive 5 mg melatonin tablets produced by Jalinous Iranian Pharmaceutical Company at a dose of 5 mg once a day for 10 days.
Category
Treatment - Drugs

2

Description
Control Group: Patients will receive standard antibiotic treatment for urinary tract infection for 10 days, along with a placebo of 5 mg melatonin tablets produced by the Iranian pharmaceutical company Jalinos, which has a similar appearance to the active drug, taking one tablet daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Kabir Hospital
Full name of responsible person
Mohsen Felegari
Street address
Amir Kabir Hospital., Nurse Square.,Shahid Shiroudi St.
City
Arak
Province
Markazi
Postal code
3819693181
Phone
+98 86 3313 4715
Fax
+98 86 3313 2510
Email
amirkabir-hospital@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Behzad Khansari Nejad
Street address
Arak University of Medical Sciences Headquarters., Alam El Hoda St.,Shahid Shiroudi St.
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3383 8319
Fax
+98 86 3417 3645
Email
research@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Amirvali Azodzadeh Ardakani

Position
assistant

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Amirkabir Hospital., Shahid Shiroudi St., Nurse Square.

City
Arak

Province
Markazi

Postal code
3819693181

Phone
+98 86 3313 4715

Fax
+98 86 3313 2510

Email
azodzadeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Ali Arjamand Shabestari

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

Street address
Amirkabir Hospital., Shahid Shiroudi St., Nurse Square.

City
Arak

Province
Markazi

Postal code
3819693181

Phone
+98 86 3313 4715

Fax
+98 86 3313 2510

Email
aliarjmand1@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Amirvali Azodzadeh Ardakani

Position
Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Amirkabir Hospital., Parasart Square., Shahid Shiroudi St.

City
Arak

Province
Markazi

Postal code
3819693181

Phone
+98 86 3313 4715

Fax
+98 86 3313 2510

Email
azodzadeh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available