

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of melatonin on the course of treatment and complications of sepsis in infants

Protocol summary

Study aim

The effect of melatonin on the course of treatment and complications of sepsis in infants

Design

This study will be a clinical trial, phase 3 and with no blinding. In this study, 50 infants under 28 days with sepsis based on Cochran's formula (25 infants in the intervention group and 25 infants in the control group) will be randomly entered into the study. Both groups will initially be matched for WBC, CRP, gestational age, patient gender, patient weight, and symptoms. In the neonatal intervention group, in addition to antibiotics, they will receive melatonin tablets at a dose of 3 mg every 12 hours for 3 days.

Settings and conduct

This study will be performed in the neonatal ward and neonatal intensive care ward. At the beginning of the diagnosis of sepsis and 72 hours after treatment, 5 cc of blood samples will be taken.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Parental consent 2- Infants under one month of age 3- Diagnosis of sepsis according to clinical and laboratory criteria 4- No patient being NPO 5- Absence of underlying diseases such as Down syndrome and ... 6- Infants with a gestational age of 37 weeks and above Exclusion criteria: 1- Dissatisfaction of parents 2- Death of the patient during melatonin administration 3- Existence of congenital anomalies 4- Existence of symptoms of Severe sepsis 5- Presence of congenital heart diseases 6- PO intolerance and frequent vomiting

Intervention groups

Melatonin tablets will be prescribed for infants under 28 days of age

Main outcome variables

Faster recovery from sepsis, prevention of complications of neonatal sepsis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210825052289N1**

Registration date: **2021-09-14, 1400/06/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-14, 1400/06/23**

Update count: **0**

Registration date

2021-09-14, 1400/06/23

Registrant information

Name

Armin Ghahremanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3325 2251

Email address

drarminghahreman@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2021-11-11, 1400/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin on the course of treatment and complications of sepsis in infants

Public title

Evaluation of the effect of melatonin in the treatment of sepsis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Parental consent Infants under one month of age
Diagnosis of sepsis according to clinical and laboratory criteria NPO patient(Non Pre Oral) absence of any underlying disease infants with gestational age above 37 weeks

Exclusion criteria:

Parental dissatisfaction Death of the patient during melatonin administration Existence of congenital anomalies Existence of severe sepsis Presence of congenital heart disease PO intolerance and frequent vomiting

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

At the beginning of the diagnosis of sepsis and 72 hours after treatment 5 cc blood sample will be taken.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be enrolled randomly in to one of the groups based on inclusion criteria. Randomisation sequence will be processed by Microsoft Excel program via (RANDBETWEEN) command and numbers 0 and 1 will be allocated to each group to choose the group of the subject.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

The aim of this study is , reduce hospitalization time and help improve neonatal sepsis treatment to prevent further complications.

Secondary Ids

empty

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

Ethic committee of Ardabil University of Medical Sciences

Street address

Moallem Ave., Ardabil Town Bouali hospital

City

Ardabil

Province

Ardabil

Postal code

5613643197

Approval date

2021-08-09, 1400/05/18

Ethics committee reference number

IR.ARUMS.REC.1400.160

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

sepsis in neonates

ICD-10 code

P36.9

ICD-10 code description

Bacterial sepsis of newborn, unspecified

Primary outcomes**1****Description**

White blood cell

Timepoint

At the beginning of treatment and 3 days after treatment

Method of measurement

Acquiring venous blood sample

2**Description**

C-Reactive Protein

Timepoint

At the beginning of treatment and 3 days after treatment

Method of measurement

Acquiring venous blood sample

3**Description**

Interleukin-6

Timepoint

At the beginning of treatment and 3 days after treatment

Method of measurement

Acquiring venous blood sample

Secondary outcomes

1

Description

Neonates general status

Timepoint

At the beginning of treatment and 3 days after treatment

Method of measurement

Based on Attending's evaluation in 3 categories: Well, Ill and Toxic

2

Description

Poorfeeding

Timepoint

At the beginning of treatment and 3 days after treatment

Method of measurement

Based on Attending's evaluation

3

Description

Outcome

Timepoint

Upon discharge

Method of measurement

Death or Living based on Attending's evaluation

4

Description

Length of hospital stay

Timepoint

Upon discharge

Method of measurement

Based on date's submitted to patient profile

Intervention groups

1

Description

Intervention group: Patients of this group will receive Melatonin tablet from Normlife Company every 12 hours for 3 days.

Category

Treatment - Drugs

2

Description

Control group: Patients of this group will not receive Melatonin tablet.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali hospital

Full name of responsible person

Armin Ghahremanzadeh

Street address

Moallem ave., Ardabil City

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Postal code

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Email

Bouali@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Aziz Kamran

Street address

Moallem Ave., Ardabil Town

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Email

Bouali@arums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Armin Ghahremanzadeh

Position

Medical Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Armin Ghahremanzadeh

Position

Pediatrics Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

All information is shareable

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

Available to university researchers.

Under which criteria data/document could be used

Can be used for similar research

From where data/document is obtainable

by Email Darminghahreman@gmail.com

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

Have a letter of recommendation from the desired university.

Comments