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
City
Ardabil
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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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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
Street address
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Person responsible for updating data

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Latest degree
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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 Drarminghahreman@gmail.com
What processes are involved for a request to access data/document
Have a letter of recommendation from the desired university.
Comments