

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparing the effectiveness of melatonin with placebo in reducing the level of interleukin-6 in operated infants.

Protocol summary

Study aim

Since inflammation is one of the most common and debilitating side effects in children undergoing surgery and disrupts the quality of life of infants, it is necessary to provide drugs to reduce their inflammation, as melatonin relieves sleep and reduces inflammation, for this reason, to prove the hypothesis that melatonin can reduce We use this medicine to create an inflammatory response.

Design

The study has a control group with a blinded and randomized parallel group in phase 3 on 40 patients and the rand function of Excel software was used for randomization.

Settings and conduct

The control group was prescribed melatonin 0.1 mg/kg for 3 days from the day before the operation to the day after the operation, and on the third day after the operation, the level of interleukin 6.esr.cr was measured, and the control group was given routine drugs with placebo (normal saline) at the same time. The amount of 0.1mg/kg is given, then the level of the mentioned inflammatory factors is measured.

Participants/Inclusion and exclusion criteria

The conditions for entering the study are the age limit of less than one month and have been hospitalized due to surgery, and have the consent of the family to enter the plan, and the conditions of not entering the hospitalization plan are not due to surgery, and in the case of surgery, serious problems such as sepsis, meningitis, corona, severe cardiopulmonary problems, abnormality have fatal and incurable diseases and lack of consent to enter the project.

Intervention groups

The intervention on facial surgery babies, which is on the level of interleukin 6.esr.crp, and blood cultures of both the control group that receives melatonin and the control group that receives placebo is done before and after the operation.

Main outcome variables

Inflammatory factors/melatonin/interleukin 6/infants/reduction of inflammation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200109046061N2**

Registration date: **2023-07-21, 1402/04/30**

Registration timing: **prospective**

Last update: **2023-07-21, 1402/04/30**

Update count: **0**

Registration date

2023-07-21, 1402/04/30

Registrant information

Name

Elnaz Nobakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8617 5194

Email address

dr.elnaznobakht@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of melatonin with placebo in reducing the level of interleukin-6 in operated infants.

Public title
Comparing the effectiveness of melatonin with placebo in reducing the level of interleukin-6 in operated infants.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age limit below one month Hospitalized for surgery
Consent of the family to participate in the plan
Exclusion criteria:

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization in the form of sequential production, where the number of subjects in each block is set to 4, and letters A are for the intervention group and letters B are considered for the control group. Finally, 20 samples (5 blocks) were produced in both groups A and B, then the cards containing the blocks were placed inside the standard envelope, thus concealing the allocation of compliance Based on the referral of eligible infants, an envelope will be taken by the researcher and the method of allocation will be determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding of the clinical caregiver who gives the medicine to the newborns, who randomly put the medicine in the caregiver's possession and will not know the contents of the medicine, and the analyzer will not know about the contents of the envelope.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Look up details 64 / 5,000 Translation results
Translation result Tehran, Shariati St. above Hosseinieh Ershad Mofid Children's Hospital

City

Tehran

Province

Tehran

Postal code

15511415468

Approval date

2023-06-25, 1402/04/04

Ethics committee reference number

IR.SBMU.MSP.REC.1402.179

Health conditions studied

1

Description of health condition studied

Severity of inflammation in operated babies

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of melatonin on reducing the level of interleukin 6

Timepoint

Day before surgery. Day three after surgery

Method of measurement

Kate Eliza

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The melatonin used in this intervention is Emivital drops from Amin company and contains one milligram of melatonin in each cc.

Category

Treatment - Drugs

2

Description

Control group: Placebo, which is administered with the same amount of drug (melatonin) 0.1 mg/kg of normal saline for 3 days from the day before surgery to two days after surgery.

Category

Placebo

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

Mofid Hospital's neonatal intensive care unit

Full name of responsible person

Elnaznobakht

Street address

Shariati St., above Hosseiniye Irshad, Mofid Children's Hospital

City

Tehran

Province

Tehran

Postal code

1546815514

Phone

+98 21 2222 7021

Email

dr.elnaznobakht@gmail.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Abdullah Karimi

Street address

Shariati St., above Hosseini Ershad, Mofid Hospital

City

Tehran

Province

Tehran

Postal code

1546815514

Phone

+98 915 501 0249

Email

dr.elnaznobakht@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elnaznobakht

Position

Pediatric clinical assistant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Saadat Abad, Blvdria, Moj St., 6 West Tawheed Alley

City

Tehran

Province

Tehran

Postal code

1466975699

Phone

+98 21 8617 5194

Email

dr.elnaznobakht@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elnaznobakht

Position

Pediatric clinical specialist assistant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Saadat Abad, Blvdria, Moj Alley, 6 West Tawheed St

City

Tehran

Province

Tehran

Postal code

1466975699

Phone

+98 21 8617 5194

Email

dr.elnaznobakht@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elnaznobakht

Position

Pediatric clinical specialist assistant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Saadat Abad, Blvdria, Moj Alley, 6 West Tawheed St

City

Tehran

Province

Tehran

Postal code

1466975699

Phone

+98 21 8617 5194

Email

dr.elnaznobakht@gmail.com

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

Patient information, including the rate of therapeutic response to melatonin to reduce the inflammatory factor in infants undergoing surgery, and how to use melatonin and placebo drugs, which are recorded by a questionnaire and finally analyzed, and the informed consent of the parents of the infants indicating that the company in the study can be shared, but the names of the participants in the study to protect the patient's privacy. It is not placed.

When the data will become available and for how long

The beginning of the access period is after the end of the registration of the results.

To whom data/document is available

It will be available for everyone

Under which criteria data/document could be used

To access this study, use the keywords melatonin, interleukin-6 and surgery

From where data/document is obtainable

Submit your requests by email to
dr.elnaznobakht@gmail.com

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

The request should be sent to the email of the person responsible for the study

Comments