

# 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**

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**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**

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**Province**

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**Postal code**

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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**

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

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**Province**

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**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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Elnaznobakht

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Postal code**

1466975699

**Phone**

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**Email**

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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**

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**