

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Investigating The Effect Of Melatonin On Infantile Colic

Protocol summary

Study aim

Investigating The Effect Of Melatonin On Infantile Colic

Design

A clinical trial; without a control group; a sample size of 69 infants using the formula; phase 2

Settings and conduct

In this study, which was conducted on 69 infants with infant colic, the infants were treated with melatonin at a minimum dose of 1 mg for one week, and after the end of the treatment period and one week after that, according to the Wessle criteria, duration of crying and restlessness were evaluated. This study was conducted in medical centers of Yazd

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mature infants; Birth weight should be between 2,500 grams and 4,000 grams; Breastfeed; Growth and weight growth charts and head circumference relative to age should be normal; Be diagnosed with Wessel criteria by a pediatrician; Exclusion criteria: The presence of other diseases in the digestive system; Use of medication that affects the treatment.

Intervention groups

For sampling, after ruling out other causes and diagnosing infantile colic by a pediatrician and obtaining informed consent from the parents, the infant entered the study and the duration of infantile colic attacks was recorded. The infant was prescribed melatonin tablets with a minimum dose of 1 mg/dl at 6 pm every day for one week.

Main outcome variables

Duration of colic; Severity of symptoms; Number of colic attacks per week;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080930001285N2**

Registration date: **2023-07-04, 1402/04/13**

Registration timing: **retrospective**

Last update: **2023-07-04, 1402/04/13**

Update count: **0**

Registration date

2023-07-04, 1402/04/13

Registrant information

Name

mehrdad shakiba

Name of organization / entity

shahid sadoghi hospital

Country

Iran (Islamic Republic of)

Phone

+98 913 151 8475

Email address

shakiba@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2019-03-19, 1397/12/28

Trial completion date

2019-03-19, 1397/12/28

Scientific title

Investigating The Effect Of Melatonin On Infantile Colic

Public title

Investigating The Effect Of Melatonin On Infantile Colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

It was diagnosed with Wessel Criteria.

Exclusion criteria:

The presence of other diseases of the digestive system
Use of medication that affects the treatment

Age

From **7 days** old to **6 months** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **69**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Sadoughi University of
Medical Sciences

Street address

Central Administration, Bahonar Sq., Yazd, I.R Iran

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2018-03-12, 1396/12/21

Ethics committee reference number

IR.SSU.MEDICINE.REC.1397.058

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

Infantile colic

ICD-10 code

R10.4

ICD-10 code description

Infantile colic

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

Having infantile colic based on Wessle criteria

Timepoint

At the beginning of the intervention and 7 and 14 days
later

Method of measurement

Calling the infants's parents and checking for symptoms
of infantile colic and recording information

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For sampling, after ruling out other
causes and diagnosing infantile colic by a pediatrician
and obtaining informed consent from the parents, the
infant entered the study, and the duration of infantile
colic attacks (infant crying) was recorded, and for the
infant, melatonin tablets with a dose of 1 mg/dl
(minimum dose) was prescribed at 6 pm every day for
one week. After one week, the infant's parents were
contacted by phone and the infant was evaluated for the
presence of symptoms of infantile colic and the changes
after taking the drug, and the group that recovered
completely was evaluated again for the symptoms of
infantile colic one week after the end of the treatment
period.

Category

Treatment - Drugs

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

Medical centers of Yazd city

Full name of responsible person

Mehrdad Shakiba

Street address

Shahid Sadoughi Hospital, Ebne Sina Blvd, Shahid
Ghandi Blvd,

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shakiba@ssu.ac.ir

Web page address

https://www.ssu.ac.ir

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

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaiee

Street address

Shahid Sadoughi Hospital , Ebne Sina Blvd, Shahid
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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

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Mehrdad Shakiba

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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

Yazd University of Medical Sciences

Full name of responsible person

Mehrdad Shakiba

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Associate Professor

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only a part of the data, such as information about the main consequence or the like, can be shared.

When the data will become available and for how long

After publishing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

To complete the data

From where data/document is obtainable

shakiba@ssu.ac.ir

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

Send request to email

Comments