The effect of Melatonin treatment for chronic insomnia one to three years old children

Protocol summary

Study aim
The effect of melatonin treatment on one-to-three-year-old children suffering from chronic insomnia

Design
A randomized single-blind clinical trial with a parallel group design

Settings and conduct
Children with chronic insomnia visiting the sleep disorder clinic will randomly receive either placebo or melatonin.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children aged between one and three years old with chronic insomnia Not having taken antibiotics, antihistamines, and hypnotic drugs during a period of one month prior to the study Exclusion criteria: Children with neurological and developmental disorders Children suffering from chronic disease (e.g., heart, kidney, and gastrointestinal) Children with anemia and blood disease Reflux

Intervention groups
The children in the experimental group will receive 0.1 mg/kg of melatonin at 7 p.m. every day, while the children in the control group will take a corresponding dose of placebo following the same protocol.

Main outcome variables
Sleep duration; sleep quality; frequent waking

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20180719040526N1
Registration date: 2018-09-29, 1397/07/07
Registration timing: registered_while_recruiting

Registrant information
Name: khatereh khamenehpour
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2018-11-21, 1397/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Melatonin treatment for chronic insomnia one to three years old children

Public title
The effect of melatonin in children insomnia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
children aged between one and three years old Chronic insomnia Not having taken antibiotics and antihistamines and hypnotic drugs over a period of one month before the treatment
Exclusion criteria:
Children suffering from neurological and developmental disorders Children with chronic disease (e.g., heart, kidney, gastrointestinal) Children suffering from anemia and blood disease Reflux

Age
From 1 year old to 3 years old

Gender
Both

Phase
3

Groups that have been masked
• Participant
• Care provider
• Outcome assessor
• Data analyser

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
Sixty numbers will be randomly generated using Microsoft Excel through simple randomization. These numbers are randomly assigned to the children participating in the study. Odd- and even-numbered children will be prescribed in black and blue ink, respectively. Melatonin and placebo pills will be placed in black and blue bottles, respectively, before being provided to a pharmacist blind to the details of the study. The pharmacist will be asked to give the bottles to the patients referred to her making sure the color of the bottle agrees with the color in which the prescription has been written.

Blinding (investigator's opinion)
Double blinded

Blinding description
The numbers randomly generated will be given to a physician at a clinic who is asked to prescribe odd-numbered patients in black ink and even-numbered patients in blue ink. Melatonin and placebo pills will be placed in black and blue bottles, respectively, before being provided to a pharmacist blind to the details of the study. The pharmacist will be asked to give the bottles to the patients referred to her making sure the color of the bottle is the same as the color in which the prescription has been written.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Eticts committee of Qazvin university of medical science

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Dept. of research Qazvin University of Medical Sciences Shahid Beheshti, Ave'

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Province
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Postal code
3415613911

Approval date
2017-10-17, 1396/07/25

Ethics committee reference number
IR.QUMS.REC.1396.277

Health conditions studied

1

Description of health condition studied
insomnia

ICD-10 code
G47.0

ICD-10 code description
Insomnia

Primary outcomes

1

Description
Sleep initiation

Timepoint
Immediately before the treatment and one month after going on melatonin

Method of measurement
Pediatric sleep clinic questionnaire: Background information

2

Description
Sleep duration

Timepoint
Immediately before the treatment and one month after going on melatonin

Method of measurement
Pediatric sleep clinic questionnaire: Background information

3

Description
Sleep quality

Timepoint
Immediately before the treatment and one month after going on melatonin

Method of measurement
Pediatric sleep clinic questionnaire: Background information

Description
Frequent waking

Timepoint
Immediately before the treatment and one month after going on melatonin

Method of measurement
Pediatric sleep clinic questionnaire: Background information

Secondary outcomes

1
Description
Weight

Timepoint
Immediately before the treatment and one month after going on melatonin

Method of measurement
Digital weighing scale

Intervention groups

1
Description
Experimental group: 0.1 mg/kg of melatonin (Nature Made, USA) on a daily basis for one month

Category
Treatment - Drugs

2
Description
Control group: 0.1 mg/kg of placebo (... , Iran) on a daily basis for one month

Category
Placebo

Recruitment centers

1
Recruitment center
Qods Hospital

Full name of responsible person
Shabnam Jalilghadr

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Sponsors / Funding sources

1
Sponsor

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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
Qazvin 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

2
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Qazvin 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available