

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of foot reflexology on quality of sleep in High Risk pregnant Women

Protocol summary

Study aim

The effect of foot reflexology on quality of sleep in High Risk pregnant Women

Design

For random allocation according to whether the two methods of therapy (massage the soles of the feet, care treatment, rutin) were from block 4 triad will be used. to block 4 triad six different modes , there are (AAaa , aaAA , AaAa , AaaA , aAaA , aAAa) this way , the scenarios on the six cards written and in the inside of abag , thrown will to choose 72 people card , from the bag out and arrange it on a tab will be written .at the time of sampling to arrange the writhen samples in the control group and the intervention amy.

Settings and conduct

Hospital Cosar, Unit Preneotal

Participants/Inclusion and exclusion criteria

1.معیارهای ورود به مطالعه 2.Gestation age 28-32 week pregnancy 3.The ability to access and track در مطالعه 4.عدم تمایل به شرکت در مطالعه 1.The lack of desire to participate in the study 2.There in nervous and mental diseases known to said patient 3.There are diseases that cause paresthesia of the lower extremities be 4.A history of diabetes, more than 10 years 5.The consumption of drugs, psychotropics and hypnotics 6.Restless leg syndrome

Intervention groups

Gestation age 28-32 week pregnancy

Main outcome variables

Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180514039650N1**

Registration date: **2018-06-09, 1397/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-09, 1397/03/19**

Update count: **0**

Registration date

2018-06-09, 1397/03/19

Registrant information

Name

Masumeh Nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3366 0805

Email address

m.nasiri@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-24, 1396/09/03

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

2017-11-24, 1396/09/03

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on quality of sleep in High Risk pregnant Women

Public title

The effect of foot reflexology on quality of sleep in High Risk pregnant Women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having literacy of reading and writing Gestation age 28-32 week The ability to access and track

Exclusion criteria:

The lack of desire to participate in the study There in nervous and mental diseases known There are diseases that cause paresthesia of the lower extremities be A history of diabetes, more than 10 years The consumption of drugs, psychotropics and hypnotics Restless leg syndrome

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation according to whether the two methods of therapy (massage the soles of the feet, care treatment, rutin) were from block 4 triad will be used. to block 4 triad six different modes , there are (AAaa , aaAA , AaAa , AaaA , aAaA , aAAa) this way , the scenarios on the six cards written and in the inside of abag , thrown will to choose 72 people card , from the bag out and arrange it on a tab will be written .at the time of sampling to arrange the writhen samples in the control group and the intervention amy.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2017-11-04, 1396/08/13

Ethics committee reference number

IR.QUMS.REC.1396.305

Health conditions studied

1

Description of health condition studied

Check the sleep disorder in pregnant women high risk

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

Primary outcomes

1

Description

Pregnant women high risk that the score questionnaire sleep Espine Coline under 19.

Timepoint

En Before and after intervention

Method of measurement

Questionnaire sleep ESpie Coline

Secondary outcomes

1

Description

The quality of sleep of pregnant women high risk

Timepoint

En After intervention

Method of measurement

Questionnaire sleep ESpie Coline

Intervention groups

1

Description

Intervention group: The intervention group additionally received the usual Care, Medical weeks, 2 to 4 weeks reflexology foot will receive, So that, was asked in a comfortable position used, then the hands to a moisturizing cream, dipped and duration 15 minute massage each foot by the researcher was done(for both feet 30 minutes), the instrument to measure the quality of sleep four weeks after the first intervention(immediately after the last session), the intervention re measured.

Category

Prevention

2

Description

Control group: only routine Care Medical was done

without the intervention, the quality of sleep at the end of the intervention, the re measured.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin Cosar Hospital

Full name of responsible person

Zahra Hoseini Golafshani

Street address

Qazvin university of medical sciences, Bahonar Blvd.,
Qazvin city

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Email

z.hoseinigolafshani@qums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peymani

Street address

Qazvin University of Medical Sciences Shahid
Beheshti, Ave' 3415613911 Qazvin' IRAN

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Fax

Email

apeymani@qums.ac.ir

Web page address

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

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Hoseini Golashani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Zahra Hoseini Golafshani

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Other areas of specialty/work
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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

En All the data have code to identify.

When the data will become available and for how long

2018

To whom data/document is available

En Qazvin University of Medical Sciences

Under which criteria data/document could be used

En By confirmation of Qazvin University of Medical Sciences

From where data/document is obtainable

En Qazvin University of Medical Sciences

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

En Refer to Qazvin University of Medical Sciences or sending email to z.hoseinigolafshani@qums.ac.ir

Comments