Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of KI-3. HT-7. ST-36. PC-6, anmian I, GB-20, DU-20 acupuncture on relieving insomnia in pregnant woman

Protocol summary

Study aim

To evaluate the effect of acupuncture on insomnia in pregnant women by the measuring urine melatonin before and after acupuncture, so that we can introduce effective method for treatment of insomnia in pregnancy

Design

72 subjects with sleep disorder will be assigned into 2 groups with Block randomization method, 36 patients will be treated by Acupuncture and sleep hygiene and 36 patients will be received only hygiene.

Settings and conduct

Before start of treatment the patients will be ask to collect a night urine sample at 23-24 pm. The acupuncture treatment will be performed 3 times a week by an acupuncturist, making at least 10 sessions. At the end of treatment again patients is ask to collect a night urine sample and also refuel sleep questionnaire and efficacy Acupuncture and sleep hygiene will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-45 years. Gestational aged between 12 and 36 weeks Women with Pittsburgh sleep quality index score more than 5. Exclusion criteria: Patients must not have suffered from insomnia before pregnancy. Patients must not have been treated by acupuncture within the preceding year. Patients must not have high risk pregnancy Patient must not have been taking hypnotic drugs.

Intervention groups

72 subjects with sleep disorder will be assigned into 2 groups with Block randomization method, 36 patients will be treated by Acupuncture and sleep hygiene and 36 patients will be received only hygiene. Before start of treatment the patients will be ask to collect a night urine sample at 23-24 pm. The acupuncture treatment will be performed 3 times a week by an acupuncturist, making at least 10 sessions.

Main outcome variables

Finally, urinary melatonin levels are compared before and after acupuncture treatment and sleep hygiene and the effectiveness of this treatment is evaluated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140525017827N3**
Registration date: **2017-12-10, 1396/09/19**
Registration timing: **prospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **1**

Registration date

2017-12-10, 1396/09/19

Registrant information

Name

Nasrin Asadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 2365

Email address

asadin@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University Of medical Science

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of KI-3. HT-7. ST-36. PC-6, anmian I, GB-20, DU-20 acupuncture on relieving insomnia in pregnant woman

Public title
The effect of acupuncture on insomnia in pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria: Women with aged between 20-45 years. Gestational aged between 12 and 36 weeks Women with Pittsburgh sleep quality index score more than 5. Exclusion criteria: Patients must not have suffered from insomnia before pregnancy. Patients must not have been treated by acupuncture within the preceding year. Patients must not have high risk pregnancy (multifetal pregnancy, threated abortion, preeclampsia, ...) Patient must not have been taking hypnotic drugs

Exclusion criteria:

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

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 Shiraz University of Medical Sciences

Street address
Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz

City
Shiraz

Province
Fars

Postal code
34786-71946

Approval date
2017-07-20, 1396/04/29

Ethics committee reference number
IR.SUMS.MED.REC.1396.77

Health conditions studied

1

Description of health condition studied
Nonorganic insomnia

ICD-10 code
F51.0

ICD-10 code description
maternal disorders predominantly related to pregnancy

Primary outcomes

1

Description
Measurment of urine Melatonine

Timepoint
before and after treatment

Method of measurement
ELISA

Secondary outcomes

empty

Intervention groups

1

Description
10 sessions of 20 minutes acupuncture

Category
Treatment - Drugs

2

Description
Observe 14 health issues

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Hafez Clinic of Shiraz University of Medical Sciences

Full name of responsible person
Saeedeh Froghinia

Street address
Shahid Chamran blvd, Hafez Clinic

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3612 8257

Email
sd.foroughinia@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University Of medical Science

Full name of responsible person
Dr Seyed Baser Hashemi

Street address
Building of Shiraz University of Medical Sciences, Zand Ave

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3230 5410

Email
hashemib@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz University Of medical Science

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
Shiraz University of Medical Sciences

Full name of responsible person
Saaedeh Froghinia

Position
Resident of obstetrics and gynecology

Latest degree
Specialist

Other areas of specialty/work

Street address
Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3612 8258

Fax

Email
sd.foroughinia@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Nasrin asadi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3612 8258

Fax

Email
nasadi2012@yahoo.ca

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin asadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

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Phone

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Fax

Email

nasadi2012@yahoo.ca

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

IPD: Information and research data Ethic form: Complete the Ethic form by the patient

When the data will become available and for how long

IPD: 2018 Ethic form: 2018

To whom data/document is available

IPD: Researcher & Patient Ethic form: Patient

Under which criteria data/document could be used

IPD: Ethic form: Awareness of test results

From where data/document is obtainable

IPD: OB & Gyn ward Shiraz university of medical sciences Ethic form: OB & Gyn ward Shiraz university of medical sciences

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

IPD: Vice chancellery Ethic form: Vice chancellery

Comments