Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparison of the effect of Reflexology on solar plexus and pressure on the P6 (Neiguan) point on the severity of nausea and vomiting pregnancy

Protocol summary

Study aim

Comparison the Effect of Solar plexus Reflexology and P6 Point Acupressure on the Severity of Nausea and Vomiting of Pregnancy

Design

A total of 135 pregnant women with nausea and vomiting will be selected and will be randomly assigned into 3 groups (acupressure P6, solar plexus reflexology, control). Randomization will be done using a block randomization method. Rhodes questionnaire will be used to measure the intensity of nausea and vomiting during the 4 days of intervention.

Settings and conduct

135 pregnant women with nausea and vomiting were selected and assigned into tree interventions groups using a block randomization method. In addition to diet, acupressure and reflexology will be used in 4th-7th day.Rhodes index questionnaire is used to measure the intensity of nausea and vomiting during the 4 days of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18-35 years old؛ single pregnancy؛ first trimester of pregnancy ؛presence of moderate to severe nausea and vomiting؛ Normal electrolyte؛ willing to participate in the study. Exclusion criteria:unwanted pregnancy; gastrointestinal diseases; cigarette smoking; presence of ketonuria.

Intervention groups

Intervention group 1: Reflexology is administered by a researcher, for 4 days. We will have one session every day that lasts nearly 20 minutes. Intervention group 2: Pressure on P6 (acupressure) that is 3 Cun above the wrist fold between the long palmar and radius flexor muscle tendons on the palm of the hand.

Main outcome variables

nausea ؛ vomiting ؛ Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180412039276N1**
Registration date: **2018-06-24, 1397/04/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-24, 1397/04/03**
Update count: **0**

Registration date

2018-06-24, 1397/04/03

Registrant information

Name

Fateme Asadollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3822 6371

Email address

fasadollahi8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-09, 1397/02/19

Expected recruitment end date

2018-08-10, 1397/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of Reflexology on solar plexus and pressure on the P6 (Neiguan) point on the severity of nausea and vomiting pregnancy

Public title

A comparison of the effect of Reflexology on solar plexus and pressure on the P6 (Neiguan) point on the severity of nausea and vomiting pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian and resident of Mashhad Having at least reading and writing skills Single intrauterine pregnancy Gestational age less than 16 weeks based on LMP or first trimester ultrasonography Nausea with or without vomiting at least for the past three days The severity of nausea and vomiting should be mild or moderate based on the nausea and vomiting (PUQE) questionnaire.

Exclusion criteria:

Use of herbal or chemical soothing nausea and vomiting drugs The presence of a medical or obstetric condition in the current pregnancy Pregnancy after infertility Intent to terminate pregnancy Extreme psychological problems Having previous knowledge about complementary medicine Inflammation, ulcers, swelling, fractures or skin lesions in the wrists and soles History of hospitalization due to severe nausea and vomiting in pregnancy use of herbal or chemical remedies medical or obstetric disease in the current pregnancy pregnancy after infertility Intent to terminate pregnancy severe mental problems

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 135 pregnant women with nausea and vomiting will be selected and assigned into three intervention groups using a block randomization method.

Blinding (investigator's opinion)

Single blinded

Blinding description

The Patient is not aware of being in the control or intervention group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Quraishi Building , Daneshgah Ave, Mashhad, Razavi Khorasan Province , Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

91735-951

Approval date

2018-04-06, 1397/01/17

Ethics committee reference number

IR.MUMS.REC.1397.7

Health conditions studied

1

Description of health condition studied

Nausea and vomiting during pregnancy

ICD-10 code

O21.9

ICD-10 code description

Vomiting of pregnancy, unspecified

Primary outcomes

1

Description

nausea and vomiting

Timepoint

3 days before intervention and 4 days after interventions.

Method of measurement

Rhodes index (questionnaire)

Secondary outcomes

1

Description

retch

Timepoint

3 days before intervention and 4 days after interventions.

Method of measurement

Rhodes index (questionnaire)

2

Description

Anxiety

Timepoint
3 days before intervention and 4 days after interventions.
Method of measurement
DASS 21 Index

Intervention groups

1

Description
Intervention group1 (The reflexology group): the patients were considered to put only on a diet in first three days. Then they received diet and foot reflexology on solar plexus on 4th-7th days. In this group, Daily reflexology was applied by researcher for 20 minutes.
Category
Treatment - Other

2

Description
Intervention group 2 (Acupressure Point P6) : the patients were considered to put only on a diet in first three days. Then they received diet and acupressure on 4th-7th days. In this group, sea band button was applied on the Neiguan point on both wrists for 4 days.
Category
Treatment - Devices

3

Description
Control group: The control group was considered to be only on the diet during 7 days.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad No. 1 Health Center
Full name of responsible person
Dr. Nasser Amini
Street address
Health Center No. 1 of Mashhad , next to Shahrbani Township, Vakil Abad Blvd , Mashhad
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Fax
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Web page address
http://ch-mashhad1.mums.ac.ir/index.php

2

Recruitment center
Name of recruitment center
Mashhad No. 2 Health Center
Full name of responsible person
Dr. Ali Asghar Mahmoudi
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3

Recruitment center
Name of recruitment center
Mashhad No. 3 Health Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name

Grant code / Reference number
19091

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Fateme Asadollahi
Position
master of science student in midwifery
Latest degree
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Associate professor
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School of Nursing and Midwifery , Ebne Sina ave,Daneshgah street, Mashhad
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Person responsible for updating data

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
Not applicable

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable