

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 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 three 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 Shahr bani Township, Vakil Abad Blvd , Mashhad

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Mashhad

Province

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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

Street address

Mashhad Health Center No. 2, Panjrah Paeen Kheyaban Ave , Mashhad

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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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Qureishi building ,Daneshgah Ave ,Mashhad, Razavi Khorasan Province

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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
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Associate professor

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Ph.D.

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Reproductive Health

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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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Position
master of science student in midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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