

# 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 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Public title</b>                                                                                                                               | 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Purpose</b>                                                                                                                                    | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Inclusion/Exclusion criteria</b>                                                                                                               | <p><b>Inclusion criteria:</b><br/>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.</p> <p><b>Exclusion criteria:</b><br/>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</p> |
| <b>Age</b>                                                                                                                                        | From <b>18 years</b> old to <b>35 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Gender</b>                                                                                                                                     | Female                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Phase</b>                                                                                                                                      | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Groups that have been masked</b>                                                                                                               | <ul style="list-style-type: none"> <li>Participant</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Sample size</b>                                                                                                                                | Target sample size: <b>135</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Randomization (investigator's opinion)</b>                                                                                                     | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Randomization description</b>                                                                                                                  | A total of 135 pregnant women with nausea and vomiting will be selected and assigned into three intervention groups using a block randomization method.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Blinding (investigator's opinion)</b>                                                                                                          | Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Blinding description</b>                                                                                                                       | The Patient is not aware of being in the control or intervention group                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Placebo</b>                                                                                                                                    | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Assignment</b>                                                                                                                                 | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Other design features</b>                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Secondary Ids</b>                                                                                                                              | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

|                                                |                                                                             |
|------------------------------------------------|-----------------------------------------------------------------------------|
| <b>Ethics committees</b>                       |                                                                             |
| <b>1</b>                                       |                                                                             |
| <b>Ethics committee</b>                        |                                                                             |
| <b>Name of ethics committee</b>                | Ethics committee of Mashhad University of Medical Sciences                  |
| <b>Street address</b>                          | Quraishi Building , Daneshgah Ave, Mashhad, Razavi Khorasan Province , Iran |
| <b>City</b>                                    | Mashhad                                                                     |
| <b>Province</b>                                | Razavi Khorasan                                                             |
| <b>Postal code</b>                             | 91735-951                                                                   |
| <b>Approval date</b>                           | 2018-04-06, 1397/01/17                                                      |
| <b>Ethics committee reference number</b>       | IR.MUMS.REC.1397.7                                                          |
| <b>Health conditions studied</b>               |                                                                             |
| <b>1</b>                                       |                                                                             |
| <b>Description of health condition studied</b> | Nausea and vomiting during pregnancy                                        |
| <b>ICD-10 code</b>                             | O21.9                                                                       |
| <b>ICD-10 code description</b>                 | Vomiting of pregnancy, unspecified                                          |
| <b>Primary outcomes</b>                        |                                                                             |
| <b>1</b>                                       |                                                                             |
| <b>Description</b>                             | nausea and vomiting                                                         |
| <b>Timepoint</b>                               | 3 days before intervention and 4 days after interventions.                  |
| <b>Method of measurement</b>                   | Rhodes index (questionnaire)                                                |
| <b>Secondary outcomes</b>                      |                                                                             |
| <b>1</b>                                       |                                                                             |
| <b>Description</b>                             | retch                                                                       |
| <b>Timepoint</b>                               | 3 days before intervention and 4 days after interventions.                  |
| <b>Method of measurement</b>                   | Rhodes index (questionnaire)                                                |
| <b>2</b>                                       |                                                                             |
| <b>Description</b>                             | 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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9185684538

##### Phone

+98 51 3501 8011

##### Fax

##### Email

AminiN1@mums.ac.ir

##### 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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9153913153

##### Phone

+98 51 3368 3000

##### Email

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##### Web page address

<http://ch-mashhad2.mums.ac.ir>

### 3

#### Recruitment center

##### Name of recruitment center

Mashhad No. 3 Health Center

##### Full name of responsible person

Dr. Brat Ali Arabnejad

##### Street address

Mashhad No. 3 Health Center, Payam Street ,Ershad 8 blvd,Khayyam blvd, Mashhsad ,Iran

##### City

Mashhad

##### Province

Razavi Khorasan

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##### Phone

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##### Email

arabnejadba1@mums.ac.ir

##### Web page address

<http://behdasht3.mums.ac.ir/>

## 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

##### City

Mashhad

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Razavi Khorasan

**Postal code**  
91735-951

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**Email**  
tafaghodim@mums.ac.ir

**Web page address**  
<http://v-research.mums.ac.ir/>

**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

**Street address**  
No. 4, Sarafrazan 11 Blvd., Pirozi Blvd.

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## Person responsible for scientific inquiries

**Contact**

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Dr Rahele Babazade

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Associate professor

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Reproductive Health

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## Person responsible for updating data

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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