

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Effect of P6 acupressure on nausea and vomiting in pregnant women: A randomized controlled clinical trial

Protocol summary

Study aim

This study examines and compares the effect of P6 acupressure with Sea-band, and placebo with each other and control group on the severity and frequency of nausea and vomiting of pregnancy.

Design

Randomized, controlled clinical trial in which 75 pregnant women in 3 groups participated.

Settings and conduct

This study was carried out on pregnant women who received prenatal care in five public healthcare centers in Ardebil (Iran). The participants were allocated to three groups including acupressure group (n=25), placebo group (n=25), and control group (n=25).

Participants/Inclusion and exclusion criteria

Inclusion criteria: having mild to moderate nausea and/or vomiting; planned and normal pregnancy; gestational age under 20 weeks; being literate. Non inclusion criteria: symptoms of Hyperemesis Gravidarum; molar or twin pregnancy; threatened abortion; being affected by any known medical condition that might manifest with nausea or vomiting; any history of recent psychological disorders which require referring to psychologist or psychiatrist or disastrous events; taking medicine (emetic or antiemetic); smoking.

Intervention groups

In acupressure group, constant pressure was applied on P6 points by means of a wristband on both wrists for three days except while showering. Participants in the placebo group used a wristband with the same method as for acupressure group but without the pressure button. No additional intervention was done for control group. Recommendations about dietary modifications were given to all participants verbally and in written.

Main outcome variables

Nausea (frequency; duration; severity); vomiting frequency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190205042624N1**

Registration date: **2019-03-03, 1397/12/12**

Registration timing: **retrospective**

Last update: **2019-03-03, 1397/12/12**

Update count: **0**

Registration date

2019-03-03, 1397/12/12

Registrant information

Name

Sedigheh Sedigh Mobarakabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

Email address

sedighehsedigh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2006-04-17, 1385/01/28

Expected recruitment end date

2006-11-20, 1385/08/29

Actual recruitment start date

2006-04-17, 1385/01/28

Actual recruitment end date

2006-11-20, 1385/08/29

Trial completion date

2006-11-20, 1385/08/29

Scientific title

Effect of P6 acupuncture on nausea and vomiting in pregnant women: A randomized controlled clinical trial

Public title

The effect of P6 Acupressure on nausea and vomiting of pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mild to moderate nausea and/or vomiting planned and normal pregnancy gestational age under 20 weeks Being literate

Exclusion criteria:

symptoms of Hyperemesis Gravidarum (weight loss, hydration therapy, intravenous drugs, and or hospitalization for treatment of NVP) molar or twin pregnancy threatened abortion being affected by any known medical condition that might manifest with nausea or vomiting history of recent psychological disorders which require referring to psychologist or psychiatrist or disastrous events taking medicine (emetic or antiemetic) smoking

Age

From **19 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **63**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants were randomly allocated to three groups, using Random Allocation Soft-ware

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Next to Taleghani hospital; SHahid Arabi Ave, Yaman

street; SHahid CHamran highway

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2018-03-18, 1396/12/27

Ethics committee reference number

IR.SBMU.PHNM.1396.959

Health conditions studied

1

Description of health condition studied

Nausea and Vomiting of Pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Nausea of Pregnancy

Timepoint

Twice a day (midday and at night before bed) during the three days of intervention period.

Method of measurement

Daily diaries form included frequency, duration (minute), and severity of nausea [scored from 0 (no nausea) to 4 (very severe nausea)] and frequency of vomiting

2

Description

Vomiting of Pregnancy

Timepoint

Twice a day (midday and at night before bed) during the three days of intervention period.

Method of measurement

Daily diaries form included frequency of vomiting

Secondary outcomes

1

Description

Overall rate of response to treatment for nausea and vomiting

Timepoint

after intervention

Method of measurement

Questionnaire (overall rate of response to treatment for nausea and vomiting separately [scored from 0 (significantly worse) to 4 (significantly better)])

2

Description

applying dietary modification

Timepoint

after intervention

Method of measurement

Questionnaire (applying dietary modifications (yes, almost, no))

3

Description

satisfaction from treatment

Timepoint

after intervention

Method of measurement

Questionnaire (satisfaction from treatment (yes, almost, no))

Intervention groups

1

Description

Intervention group: Acupressure group received pressure on P6 with Sea-band button for 3 days

Category

Treatment - Devices

2

Description

Control group: applied Sea-band without pressure on P6

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bakeri public healthcare center in Ardebil

Full name of responsible person

Giti Ozgoli

Street address

Department of Midwifery and Reproductive Health,
School of Nursing and Midwifery, Niayesh Highway,
Vali-asr Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Fax

+98 21 8820 2521

Email

gitiozgoli2017@gmail.com

2

Recruitment center

Name of recruitment center

Javid Mohseni public healthcare center in Ardebil

Full name of responsible person

Giti Ozgoli

Street address

Department of Midwifery and Reproductive Health,
School of Nursing and Midwifery, Niayesh Highway,
Vali-asr Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Fax

+98 21 8820 2521

Email

gitiozgoli2017@gmail.com

3

Recruitment center

Name of recruitment center

Jedi public healthcare center in Ardebil

Full name of responsible person

Giti Ozgoli

Street address

Department of Midwifery and Reproductive Health,
School of Nursing and Midwifery, Niayesh Highway,
Vali-asr Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Fax

+98 21 8820 2521

Email

gitiozgoli2017@gmail.com

4

Recruitment center

5

Recruitment center

Name of recruitment center

Mirza Hoseini public healthcare center in Ardebil

Full name of responsible person

Giti Ozgoli

Street address

Department of Midwifery and Reproductive Health,
School of Nursing and Midwifery, Niayesh Highway,
Vali-asr Street, Tehran, Iran

City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Fax
+98 21 8820 2521
Email
gitiozgoli2017@gmail.com

6

Recruitment center

Name of recruitment center
Akhari public healthcare center in Ardebil
Full name of responsible person
Giti Ozgoli
Street address
Department of Midwifery and Reproductive Health,
School of Nursing and Midwifery, Niayesh Highway,
Vali-asr Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Fax
+98 21 8820 2521
Email
gitiozgoli2017@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sedigheh Sedigh Mobarakabadi
Street address
Department of Midwifery and Reproductive Health,
School of Nursing and Midwifery, Niayesh Highway,
Vali-asr Street
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Fax
+98 21 8820 2521
Email
sedighehsedigh@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sedigheh Sedigh Mobarakabadi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Department of Midwifery and Reproductive Health,
School of Nursing and Midwifery, Niayesh Highway,
Vali-asr Street
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
sedighehsedigh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sedigheh Sedigh Mobarakabadi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address

School of Nursing and Midwifery, Niayesh Highway,
Vali-asr Street

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

Sedighehsedigh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

sedigheh sedigh mobarakabadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Niayesh Highway,
Vali-asr Street

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

sedighehsedigh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Some part our spss data dystroied

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable