

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of supportive counseling by midwife with and without acupressure on nausea and vomiting in pregnant women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of supportive counseling by midwife with and without acupressure on nausea and vomiting in pregnant women

Design

This is a randomized clinical trial, phase II, in which 140 eligible pregnant women will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible pregnant women who will refer to Comprehensive Health Centers in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years; Gestational age of 8 to 10 weeks; Nausea and vomiting; Wanted pregnancy; Literate Exclusion criteria: History of acupuncture or acupressure; Mental disorders; Gastric or renal diseases; Using tobacco or alcohol; Pregnancy complications

Intervention groups

Intervention group 1: Routine care during pregnancy plus supportive counseling for 45 to 60 minutes for 3 sessions and bracelet with push button for 14 days Intervention group 2: Routine care during pregnancy plus supportive counseling for 45 to 60 minutes for 3 sessions and bracelet without push button for 14 days Intervention group 3: Routine care during pregnancy plus supportive counseling for 45 to 60 minutes for 3 sessions Control group: Just routine care during pregnancy

Main outcome variables

Primary outcome: The severity of nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N297**

Registration date: **2019-09-21, 1398/06/30**

Registration timing: **prospective**

Last update: **2019-09-21, 1398/06/30**

Update count: **0**

Registration date

2019-09-21, 1398/06/30

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supportive counseling by midwife with and without acupressure on nausea and vomiting in pregnant women: a randomized clinical trial

Public title

Effect of supportive counseling by midwife with and without acupressure on nausea and vomiting in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 35 years; Gestational age of 8 to 10 weeks; Nausea and vomiting; Wanted pregnancy; Literate

Exclusion criteria:

History of acupuncture or acupressure; Mental disorders; Gastric or renal diseases; Using tobacco or alcohol; Pregnancy complications

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to four groups through the drawing of lots. To do this, we prepare four sheets and write "A", "B", "C", and "D" on every sheet. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the four groups.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-08-10, 1398/05/19

Ethics committee reference number

IR.UMSHA.REC.1398.422

Health conditions studied**1****Description of health condition studied**

Nausea and vomiting

ICD-10 code

O21.9

ICD-10 code description

Vomiting of pregnancy, unspecified

Primary outcomes**1****Description**

The severity of nausea and vomiting

Timepoint

Before the intervention and 14 days later

Method of measurement

By history taking

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Routine care during pregnancy plus supportive counseling for 45 to 60 minutes for 3 sessions and bracelet with push button for 14 days

Category

Treatment - Other

2**Description**

Intervention group 2: Routine care during pregnancy plus supportive counseling for 45 to 60 minutes for 3 sessions and bracelet without push button for 14 days

Category

Treatment - Other

3**Description**

Intervention group 3: Routine care during pregnancy plus supportive counseling for 45 to 60 minutes for 3 sessions

Category

Treatment - Other

4

Description

Control group: Just routine care during pregnancy

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Hamadan City

Full name of responsible person

Azadeh Azadi Mghtader

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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6517838695

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+98 81 3838 0572

Email

moghtader89@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Azadeh Azadi Mghtader

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Zahra Masoomi

Position

Fertility Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Email

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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