

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the Effects of Zingiber officinale and Vitamin B6 in Nausea and Vomiting of Pregnancy in pregnant women referred to health centers in Hamadan City: A randomized clinical trial

Protocol summary

Study aim

The aim of this study is to determine the effect of Zingiber officinale and Vitamin B6 in nausea and vomiting of pregnancy in pregnant women referred to health centers in Hamadan, Iran.

Design

A randomized clinical trial, blinded, community based with a parallel group design with 80 patients, enrolled between March 2018 and June 2018

Settings and conduct

The present study is a clinical trial study with two-groups design with two stages of before and after intervention. The research Community consists of pregnant women referred to health centers in Hamadan, Iran. The research sample consisted of 80 pregnant women. The participants will randomly be assigned to one of four oral treatments groups: Zingiber officinale (240 mg/twice a day) or Vitamin B6 (40 mg/twice a day).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18-40 years; Primi Para; No history of psychological illness; non-use of psychological drugs. exclusion criteria: Unwillingness to continue cooperation; Allergy to drug useage.

Intervention groups

Intervention group: The participants will be randomly selected in one of two oral treatments groups for one week : Zingiber officinale (240 mg/twice a day) or Vitamin B6 (40 mg/twice a day)

Main outcome variables

Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110626006888N20**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **prospective**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 6051

Email address

shobeiri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Zingiber officinale and Vitamin B6 in Nausea and Vomiting of Pregnancy in pregnant women referred to health centers in Hamadan

City: A randomized clinical trial	
Public title	Comparison of the Effects of Zingiber officinale and Vitamin B6 in Nausea and Vomiting of Pregnancy in pregnant women
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Age of 18-40 years Primi Para No history of psychological illness non-use of psychological drugs
Exclusion criteria:	Unwillingness to continue cooperation Allergy to drug useage
Age	From 18 years old to 40 years old
Gender	Female
Phase	2-3
Groups that have been masked	• Participant • Investigator
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	For this work, we prepared 4 sheets of paper, writing on 2 sheets "Z" for "Zingiber officinale" and on 2 sheets "V" for "Vitamin B6."The sheets is pooled, placed in a container, and randomly drawn 1 at a time for each patient without replacement until all 4 sheets are drawn. The 4 sheets are then placed back into the container, and this action is repeated until the sample size is reached.
Blinding (investigator's opinion)	Double blinded
Blinding description	The eligible students are randomly assigned to 2 groups using the allocation concealment method. The allocations remained concealed during the study. For this purpose, the random allocation is conducted and labeled by a pharmacologist, so that neither the students nor the distributor, who elevate the effect of the interventions, are aware of the administered drugs, until the data are analyzed and the labels are decoded.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	

<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Hamadan University of Medical Sciences
Street address	No. 17, Department of Research and Technology, Hamadan University of Medical Sciences, Fahmideh street, Hamadan
City	Hamadan
Province	Hamadan
Postal code	6517838678
Approval date	2018-02-27, 1396/12/08
Ethics committee reference number	IR.UMSHA.REC.1396.836

Health conditions studied

<u>1</u>	
Description of health condition studied	Nausea and Vomiting during pregnancy
ICD-10 code	021
ICD-10 code description	Hyperemesis gravidarum, mild or unspecified, starting before the end of the 22nd week of gestation

Primary outcomes

<u>1</u>	
Description	Nausea and vomiting
Timepoint	Before the intervention and one week after the intervention
Method of measurement	PUQE-24 questionnaire

Secondary outcomes

<u>1</u>	
Description	Severity of nausea and vomiting
Timepoint	Before the intervention, and one week after the intervention
Method of measurement	PUQE-24 questionnaire

Intervention groups

1

Description

"Intervention group 1:" The participants will randomly be selected to oral treatments groups for one week : Zingiber officinale (240 mg/twice a day).

Category

Treatment - Drugs

2

Description

"Intervention group 2:" The participants will randomly be selected to oral treatments groups for one week : Vitamin B6 (40 mg/twice a day).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Hamadan city

Full name of responsible person

Fatemeh Shobeiri

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No. 17, Hamdan University of Medical Sciences,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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No. 7, Research and Technology Deputy, Hamadan
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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

Fatemeh Shobeiri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the main consequence of sharing is possible.

When the data will become available and for how long

Information on the main consequence of sharing is possible.

To whom data/document is available

Information on the main consequence of sharing is possible.

Under which criteria data/document could be used

Information on the main consequence of sharing is possible.

From where data/document is obtainable

Information on the main consequence of sharing is possible.

What processes are involved for a request to access data/document

Information on the main consequence of sharing is possible.

Comments

Information on the main consequence of sharing is possible.