Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of alipoic acid with vitamin B6 in the treatment of pregnancy nausea and vomiting

Protocol summary

Study aim
Determination of the effect of alphalipoic acid compared to vitamin B6 in the treatment of nausea and vomiting of pregnancy

Design
A controlled, parallel-group, single-blind, randomized, phase three clinical trial on 80 patients. For randomization, the formation of random blocks and the random selection of each block were used

Settings and conduct
Pregnant women who have referred to the women's clinic of Ba'ath Hospital in Sanandaj city with symptoms of nausea and vomiting of pregnancy, if they meet the inclusion criteria and do not have the exclusion criteria, they will be included in the study after obtaining written consent and explaining the objectives of the study. They are divided into two groups including: vitamin B6 group and alpha lipoic acid group. How to use the medicine correctly, side effects and how to respond to the treatment are evaluated in the next 48 hours and one week later, patients whose symptoms of vomiting and nausea are not controlled during the treatment period with the mentioned interventions and who respond properly to the intervention and need to take other antiemetic drugs during the study, they will be excluded from the study and will receive their standard treatments and will not be deprived of their routine and standard treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Gestational age (7 to 14 weeks) - Symptoms of mild to moderate Pregnancy Nausea and Vomiting Exclusion criteria: - Multiple births - PO intolerance - Gestational age below 7 and above 14 Weeks - BMI above 35 - Mothers who smoke or use Narcotics - Abnormal Pregnancy - Suffering from severe mental Disorders - Other Pathologies that cause Nausea and Vomiting in Pregnancy

Intervention groups
1. Group receiving Vitamin B 2. Alphalipoic acid receiving Group

Main outcome variables
Nausea, number of times of Vomiting and number of times of Burping

General information

Reason for update

Acronym
CEAB6

IRCT registration information
IRCT registration number: **IRCT20231226060527N1**
Registration date: **2024-10-01, 1403/07/10**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-01, 1403/07/10**
Update count: **0**

Registration date
2024-10-01, 1403/07/10

Registrant information

Name
Shina Karimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3356 0595

Email address
sh.karimi.gyn@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-06, 1403/04/16

Expected recruitment end date
2024-12-20, 1403/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of alipoic acid with vitamin B6 in the treatment of pregnancy nausea and vomiting

Public title

The effect of alphalipoic acid in nausea of pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age (7 to 14 weeks) Symptoms of mild to moderate Nausea and Vomiting during Pregnancy with a score of 3 to 12 in the The Pregnancy-Unique Quantification of Emesis and Nausea (PUQE) Questionnaire

Exclusion criteria:

Multiple births PO intolerance Gestational age below 7 weeks and above 14 weeks BMI above 35 Taking Anti-vomiting and Anti-nausea Drugs (including Metoclopramide, Ondansetron, Dimenhydranate, etc.) within 48 hours before the visit Mothers who smoke or use Narcotics Abnormal pregnancy (molar pregnancy or its history, pregnancy with anomalous or dead fetus, ectopic pregnancy) Having severe mental disorders Other Pathologies that cause Nausea and Vomiting in Pregnancy: Gastroenteritis, Gastroparesis, Intestinal obstruction, Bile duct disease, Pancreatitis, Hepatitis, Gastric ulcer, Appendicitis, Pyelonephritis, Ovarian torsion, Urinary tract Stones, Diabetic Ketoacidosis, Patients with previous history Diabetes, uncontrolled gestational diabetes, Blood pressure, Liver dysfunction, Hyperthyroidism, Hyperparathyroidism, Migraine, false brain tumor, Vestibular diseases

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is based on the formation of Blocks of 4 and the random selection of each of these Blocks for every 4 new Patients entered, and the Blocks are as follows: AABB ABAB ABBA BBAA BABA BAAB First, the demographic and clinical information of the patients, including age, BMI, education, gestational age, number of births, type of pregnancy, history of nausea and vomiting during pregnancy will be collected based on the checklist (Appendix 1). Then, using random blocks of 4, the patients will be divided into two groups: 1) alpha lipoic acid and 2) vitamin B6.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the fact that the form of the drugs are not the same and the treating physician is one of the evaluators of the results, it is not possible to perform double blinding and the only person who performs the data analysis (data analyzer) will be blinded to the treatment groups. As a result, the study is one-sided blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kordestan University of Medical Sciences

Street address

3rd Floor, No. 8, Nasim Alley, Shebli Blvd.

City

Sanandaj

Province

Kurdistan

Postal code

6618984815

Approval date

2023-04-18, 1402/01/29

Ethics committee reference number

IR.MUK.REC.1402.026

Health conditions studied

1

Description of health condition studied

Pregnancy Nausea and Vomiting

ICD-10 code

O21.9

ICD-10 code description

Vomiting of pregnancy, unspecified

Primary outcomes

1

Description

The Pregnancy-Unique Quantification of Emesis and Nausea (PUQE) Questionnaire: the degree of discomfort or Nausea, the number of times of vomiting, the amount of burping in the last 12 hours

Timepoint
At the beginning of the study, 48 hours later, one week later
Method of measurement
The Pregnancy-Unique Quantification of Emesis and Nausea (PUQE) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: vitamin B6 group (recipient of vitamin B6 tablets with a dose of 25 mg orally 3 times a day for one week)
Category
Treatment - Drugs

2

Description
Intervention group: Alpha-lipoic acid group (receiver of alpha-lipoic acid capsules with a dose of 300 mg orally, twice a day for one week)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sanandaj Beethat Hospital Clinic
Full name of responsible person
Shina Karimi
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3rd Floor, No. 8, Nasim Alley, Shebli Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Afshin Melki
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3rd Floor, No. 8, Nasim Alley, Shebli Blvd.
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Sh.karimi.Gyn@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Shina Karimi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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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