Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy evaluation of concurrent Zingiber and Vitamin B6 in morning sickness of pregnant women

Protocol summary

Summary

Regarding the proper treatment of ginger in a dose of 1000 mg per day and the probability of some tolerable complications, the aim of this study is to reduce the consumption of ginger to 500 mg per day by co-administration with vitamin B6. This study is conducted on pregnant women with nausea problems that are present in their first 17 weeks of pregnancy. Criteria for entering the study are: a person with no other underlying illnesses, no other medications, No history of hospitalization for severe nausea and vomiting, lack of hyperemesis gravid arum, lack of allergy to ginger or vitamin B6 and lack of twin pregnancy or Multiplier. Exit criteria include serious adverse effects, very severe nausea, or using other anti-nausea drugs. Study is conducted in three groups: 40mg b6, 40mg b6+500mg ginger, 40mg b6+1000mg ginger per day. Each group consists of 80 people. At beginning of the assessment, the consent is filled up by the individual before the drug is started. The day of referral to the treatment center is a questionnaire filled with a person's personal information (age, degree of education, ...), degree of nausea and vomiting within 24 hours before starting treatment. The medication is delivered and the information is collected for a period of 4 days by the SMS panel or the telephone number of the person who reports the condition of the nausea and vomiting condition.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080635529N1**
Registration date: **2017-09-30, 1396/07/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-30, 1396/07/08

Registrant information

Name
Hamid-Reza Adhami
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6412 1280
Email address
hr-adhami@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy evaluation of concurrent Zingiber and Vitamin B6 in morning sickness of pregnant women

Public title

Efficacy evaluation of concurrent Zingiber and Vitamin B6 in morning sickness of pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Pregnant women with nausea or

vomiting in the first 17 weeks of pregnancy; no other underlying conditions; no other medications; no history of hospitalization due to severe nausea and vomiting; no hyperemesis gravidarum; no history of hypersensitivity to ginger or vitamin B6; non pregnancy of twin or multiplexes. Exclsion criteria: Serious complications following the use of ginger and vitamin B6; Very severe nausea (hyperemesis gravidarum) during the study, which leads to hospitalization; other drugs used to control nausea.

Age
No age limit
Gender
Female

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **240**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehtan University of Medical Sciences
Street address
Poursina st.
City
Tehran
Postal code
Approval date
2017-07-30, 1396/05/08
Ethics committee reference number
IR.TUMS.REC.1396.2950

Health conditions studied

1

Description of health condition studied
morning sickness
ICD-10 code
O21.9
ICD-10 code description
Vomiting of pregnancy, unspecified

Primary outcomes

1

Description
Severity of nausea
Timepoint
2 time daily for 4 days
Method of measurement
Qualitative

Secondary outcomes

1

Description
Reduce of vomiting severity by medication
Timepoint
2 times daily for 4 days
Method of measurement
Qualitative

Intervention groups

1

Description
Prescribing 250 mg of ginger and 20 mg of vitamin B6 orally twice daily for 4 days.
Category
Treatment - Drugs

2

Description
Prescribing 20 mg of vitamin B6 orally twice daily for 4 days.
Category
Treatment - Drugs

3

Description
Prescribing 500 mg of ginger and 20 mg of vitamin B6 orally twice daily for 4 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Female clinic- Shariati hospital
Full name of responsible person
Ashraf Aleyasin
Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Resaerch, TUMS
Full name of responsible person
Jafari
Street address
Faculty of pharmacy
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Resaerch, TUMS
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
TUMS
Full name of responsible person
Hamid-Reza Adhami
Position
Assistant professor
Other areas of specialty/work
Street address
Faculty of Pharmacy
City
Tehran
Postal code
Phone
+98 21 6412 1280
Fax
Email
hr-adhami@tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
TUMS
Full name of responsible person
Niayesh Mohebbi
Position
Assistant Professor
Other areas of specialty/work
Street address
Faculty of pharmacy
City
Tehran
Postal code
Phone
+98 21 6412 1280
Fax
Email
niayesh_mohebbi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hamid-Reza Adhami
Position
PhD Assistant Professor
Other areas of specialty/work
Street address
16th Azar st., Keshavarz Boul.
City
Tehran
Postal code
1417614411
Phone
+98 21 6412 1280
Fax
+98 21664611
Email
hr-adhami@tums.ac.ir
Web page address
www.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty