Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Jalinus syrup versus Ondansetron syrup on nausea and vomiting in pregnant women: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of Jalinus syrup versus Ondansetron syrup on nausea and vomiting in pregnant women. Design: A randomized clinical trial. Setting and conduct: The eligible pregnant women who will refer to Comprehensive Health Centers during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 40 years; singleton pregnancy; gestational age of 8 to 9 weeks; first pregnancy; desire for pregnancy; mild to moderate nausea or vomiting (with a minimum and maximum score of 3 to 12). Exclusion criteria: Taking any medication simultaneously (except folic acid); using anti-nausea and vomiting drugs within the last 24 hours; molar pregnancy; symptoms of abortion; alcohol and cigarette smoking; mental disorder; family disputes over the past 6 months; pyelonephritis; thyroid dysfunction; digestive disease. Intervention Group 1: Jalinus syrup consisting of quince fruit, ginger, vinegar and honey, made by Barij Essence Company 5 ml twice a day for 2 weeks. Intervention group 2: Ondansetron syrup, serotonin receptor antagonist, made by Oxir Pharmaceuticals Company 5 ml twice a day for 2 weeks Primary outcome: Assessing nausea and number of vomiting before intervention and one week after that using PUQE standard questionnaire. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709079014N184**
Registration date: **2017-09-19, 1396/06/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-19, 1396/06/28

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

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

Expected recruitment start date

2017-09-23, 1396/07/01

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

Comparison of the effect of Jalinus syrup versus Ondansetron syrup on nausea and vomiting in pregnant women: a randomized clinical trial

Public title

Comparison of the effect of Jalinus syrup versus Ondansetron syrup on nausea and vomiting in pregnant

women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 40 years; singleton pregnancy; gestational age of 8 to 9 weeks; first pregnancy; desire for pregnancy; mild to moderate nausea or vomiting (with a minimum and maximum score of 3 to 12). Exclusion criteria: Taking any medication simultaneously (except folic acid); using anti-nausea and vomiting drugs within the last 24 hours; molar pregnancy; symptoms of abortion; alcohol and cigarette smoking; mental disorder; family disputes over the past 6 months; pyelonephritis; thyroid dysfunction; digestive disease

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

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 the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Approval date

2017-09-02, 1396/06/11

Ethics committee reference number

IR.UMSHA.REC.1396.407

Health conditions studied

1

Description of health condition studied

Nausea and vomiting in pregnancy

ICD-10 code

O21.9

ICD-10 code description

Vomiting of pregnancy, unspecified

Primary outcomes

1

Description

Assessing nausea and number of vomiting

Timepoint

before intervention and one week after that

Method of measurement

using PUQE standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Jalinus syrup consisting of quince fruit, ginger, vinegar and honey, made by Barij Essence Company 5 ml twice a day for 2 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: Ondansetron syrup, serotonin receptor antagonist, made by Oxir Pharmaceuticals Company 5 ml twice a day for 2 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers

Full name of responsible person

Arezoo Shayan

Street address

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

City

Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences
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
School of Nursing and Midwifery
Full name of responsible person
Arezoo Shayan
Position
Master of Midwifery
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Postal code
Phone
+98 81 3838 0572
Fax
Email
arezoo.shayan2012@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
School of Nursing and Midwifery
Full name of responsible person
Arezoo Shayan
Position
Master of Midwifery
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Postal code
Phone
+98 81 3838 0717
Fax
Email
arezoo.shayan2012@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Epidemiology
Full name of responsible person
Dr Jalal Poorolajal
Position
Associate Professor
Other areas of specialty/work
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
Phone
+98 81 3838 0090
Fax
Email
poorolajal@umsha.ac.ir
Web page address

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