

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The comparison of effectiveness of psychotherapy and pharmacotherapy to improvement of nausea and vomiting of pregnancy

Protocol summary

Summary

In a randomized clinical trial 86 pregnant women above 18 years, singleton, first trimester with moderate nausea / vomiting and inform consent to enter the study will be selected. Women will be assigned randomly to two groups; either control (pharmacotherapy alone) or experimental (pharmacotherapy plus psychotherapy) group. Pharmacotherapy group will be give pyridoxine hydrochloride (40 mg daily) for 3 weeks. Experimental group will receive pyridoxine hydrochloride (40 mg daily) and psychotherapy in eight individual sessions over 3 weeks. All participants will completed the Rodeshes index of nausea, vomiting and retching (RINVR), the hospital anxiety and depression scale (HADS), and prenatal distress questionnaire (PDQ) at baseline, 3 weeks after baseline, and at 1 month post-treatment follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304035931N2**

Registration date: **2013-04-16, 1392/01/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-16, 1392/01/27

Registrant information

Name

Mahbobeh Faramarzi

Name of organization / entity

Babol University of medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

m.faramarzi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2013-02-01, 1391/11/13

Expected recruitment end date

2014-12-23, 1393/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effectiveness of psychotherapy and pharmacotherapy to improvement of nausea and vomiting of pregnancy

Public title

The comparison of effectiveness of psychotherapy and pharmacotherapy to improvement of nausea and vomiting of pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age above 18 years; singleton pregnancy and first trimester.

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: 86

Randomization (investigator's opinion)

Randomized

Randomization description

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

Babol University of Medical Sciences

Street address

Babol- Gang Afroz

City

Babol

Postal code

4715864247

Approval date

2013-01-22, 1391/11/03

Ethics committee reference number

2006

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

Naesea/vomiting

Timepoint

Beginning of the study and after 4 weeks

Method of measurement

Rodesh scale

Secondary outcomes

1

Description

anxiety and depression

Timepoint

beginning, after 3 weeks, 1 month follow-up

Method of measurement

hospital anxiety and depression scale (HADS)

Intervention groups

1

Description

This group will be given pyridoxine hydrochloride (40 mg daily) for 3 weeks.

Category

Treatment - Drugs

2

Description

Group psychotherapy , will be given treatment session 1 hour weekly for 3 weeks

Category

Treatment - Other

3

Description

Control group do not recieve any intervention except routin nutritional nausea/vomiting.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rohani hospital

Full name of responsible person

Mahbobeh faramarzi

Street address

Babol University of Medical sciences

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Mostafazadeh

Street address

Babol University of Medical Sciences

City
babol

Grant name
پژوهشی

Grant code / Reference number
2006

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

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
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Assistant professor

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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