

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of Impact of Benson Muscle Relaxation Technique on Pregnancy Nausea&Vomiting Severity.

Protocol summary

Summary

Effects of relaxation on nausea & vomiting has been shown in many studies, but relaxation has not been studied adequately in pregnancy physiologic complications. Due to the important of decreasing in nausea & vomiting of pregnant women, This study evaluates effects of Benson muscle relaxation technique on pregnancy nausea & vomiting severity . IN a quasi - experimental controlled trial and single blind, sixty pregnant women who will be 6-10 weeks of gestation, singleton pregnancy and mild and moderate induced nausea and vomiting of pregnancy and will be excluded the study after three consecutive days leaving the relaxation exercises, will be sampled. First, case group will be followed then, after one month (cleaning period), control group will be followed. On the sampling day, maternal state nausea & vomiting will be measured by using the Pregnancy Unique Quantification Emesis and nausea (PUQE) questionnaire. Interventions will be done for pregnant women in case group as 4 weeks continuously relaxation, session consisted of four identical standardized 10-15 min for two times (morning & afternoon). During interventions, will be asked the mother to again complete the PUQE questionnaire weekly. Interventions will not be done in the control group. During interventions, will be asked them to again complete the PUQE questionnaire weekly. In this study, pregnancy nausea & vomiting severity in two groups will be measured the day before interventions and 4 weeks continuously during interventions by PUQE questionnaire. then results will be compared in groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307152248N10**

Registration date: **2014-02-28, 1392/12/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-28, 1392/12/09

Registrant information

Name

Fereshteh Jahdi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00982188773073,00982182471404

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-08-06, 1392/05/15

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Impact of Benson Muscle Relaxation Technique on Pregnancy Nausea&Vomiting Severity.

Public title

The effect of relaxation on pregnancy nausea

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : singleton pregnancy with a live fetus ; no previous gastrointestinal diseases ; literacy as reading and writing ; ability to use relaxation audio CD ; lack of mental illness known as ; not taking drugs tranquilizers, anti- anxiety, anti- nausea and vomiting are now ; not getting the same period of relaxation ; spontaneous pregnancies ; not suffering spouses to alcohol and drugs and cigarettes ; dislikes stressful experiences in the three months prior to the intervention of relatives , such as the death of relatives ; having a history of bad consequences of pregnancy; 6 to 10 weeks of gestation the pregnancy based on the first day of the last menstrual period or ultrasound ; mild and moderate induced nausea and vomiting of pregnancy and Exclusion criteria:vaginal bleeding or other complications during pregnancy; need for hospitalization during the study; requested requires other therapies; stressful events during the study; use of drug that effects on anxiety during study; need to refer to a psychiatrist during the study; leaving exercises three consecutive days or more.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical commitment of Tehran University of Medical Sciences

Street address

Sixth floor ,Central office, Ghods St, Keshavarz Blvd

City

Tehran

Postal code

19964

Approval date

2013-07-23, 1392/05/01

Ethics committee reference number

306/105/92/3

Health conditions studied**1****Description of health condition studied**

Pregnancy nausea and vomiting

ICD-10 code

020-029

ICD-10 code description

Other maternal disorders predominantly related to pregnancy

Primary outcomes**1****Description**

Pregnancy nausea and vomiting severity

Timepoint

The day before interventions and 4 weeks continuously during interventions

Method of measurement

By Pregnancy Unique Quantification of Emesis and Nausea (PUQE) questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

In case group as 4 weeks continuously relaxation, session consisted of four identical standardized 10-15 min for two times (morning & afternoon) will be done.

Category

Prevention

2**Description**

Intervention Will not be done in the control group

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash Hospital of Tehran University of Medical Sciences

Full name of responsible person

Fereshteh Jahdi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sciences vice chancellor for research- Tehran
University of Medical Sciences
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Sixth floor ,Central office, Ghods St, Keshavarz Blvd-
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Tehran, Iran

Grant name

Grant code / Reference number

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

Title of funding source

Tehran 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
Tehran University of Medical Sciences, School of
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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