Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
f.jahdi@iums.ac.ir

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/د

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

Street address

Midwifery Dep, School of Nursing Midwifery, Tehran University of Medical Sciences, West Nosrat St, Tohid Sq, Tehran.Iran

City
Tehran

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

Street address
Sixth floor ,Central office, Ghods St, Keshavarz Blvd-

City
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 Midwifery and Nursing

Full name of responsible person
Fereshteh Jahdi

Position
Master of midwifery

Other areas of specialty/work

Street address
Midwifery dep, School of Nursing Midwifery, Tehran University of Medical Sciences, West Nosrat St, Tohid Sq, Tehran,Iran

City
Tehran

Postal code
4798/19395

Phone
00982188773073,00982182471404

Fax
+98 21 8879 3805

Email
f.jahdi@iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences, School of Midwifery and Nursing

Full name of responsible person
Fereshteh Jahdi

Position
Master of midwifery

Other areas of specialty/work

Street address
Midwifery Dep, School of Nursing Midwifery, Tehran University of Medical Sciences, West Nosrat St, Tohid Sq, Tehran,Iran

City
Tehran

Postal code
19395/4795

Phone
+98 21 8247 1404

Fax
+98 21 8879 3805

Email
f.jahdi@iums.ac.ir

Web page address
www.fnm.tums.ac.ir

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