

# 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  
**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  
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Master of midwifery  
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4798/19395

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences, School of  
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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*