

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effect of Physical and mental relaxation on gestational hypertension

#### Protocol summary

##### Summary

(1) Objectives: This study aims to determine the effect of physical and mental relaxation on gestational hypertension, (2) Design: This is a single blind, randomized clinical trial will be conducted in 80 pregnant women with hypertension referring to Qazvin Kosar hospitals, (3) Setting and conduction: Eligible Subjects will be selected by a convenience sampling method. Then they will be randomly assigned into two groups of 40 subjects one an intervention group (green balls) and the other a control group (blue balls), (4) Participants including major eligibility criteria: BP  $\geq$ 140/90 mmHg; Singleton pregnancy; gestational age of 20-30. And the main exclusion criteria are twin pregnancy; preeclampsia; eclampsia; HELLP syndrome; Cardiovascular; kidney, brain, blood or liver disorders, (5) Interventions: Beside the usual medical care, the intervention group should participate in advanced muscle relaxation and mental imagery classes, each session 30 minute, twice a week and for 8 weeks. The blood pressures will be measured before and after the intervention. In control group, in addition to the usual medical cares, the blood pressures will be measured twice a week, before and after a 15-min rest, (6) The main outcome measures: The Systolic and diastolic blood pressure will be assessed before and after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201604181113N4**  
Registration date: **2016-08-07, 1395/05/17**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-07, 1395/05/17

#### Registrant information

##### Name

Fatemeh Ranjkesh

##### Name of organization / entity

Qazvin University Of Medical Sciences, Nursing & Midwifery school

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 1335 9501

##### Email address

franjkes@qums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Investigator

#### Expected recruitment start date

2016-04-20, 1395/02/01

#### Expected recruitment end date

2016-07-22, 1395/05/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of Physical and mental relaxation on gestational hypertension

#### Public title

Effect of relaxation on Gestational hypertension

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Including criteria: BP  $\geq$ 140/90 mmHg; Singleton pregnancy; gestational age of 20-30 week exclusion criteria: Twin pregnancy; preeclampsia; eclampsia; HELLP syndrome; Cardiovascular, kidney, brain, blood or liver disorders.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 80

**Randomization (investigator's opinion)**

Randomized

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

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

randomized clinical trial

**Secondary Ids**

empty

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

Qazvin University of Medical Sciences

**Street address**

Bahonar boulevard, Qazvin University of Medical Sciences

**City**

Qazvin

**Postal code****Approval date**

2016-03-09, 1394/12/19

**Ethics committee reference number**

ir.qums.rec.1394.839

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

Gestational hypertension

**ICD-10 code**

013

**ICD-10 code description**

Gestational [pregnancy-induced] hypertension without significant proteinuria

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

Systolic and Diastolic blood pressure

**Timepoint**

Before and after intervention

**Method of measurement**

According to mmhg

**Secondary outcomes**

empty

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

Intervention: The intervention group should participate in advanced muscle relaxation and mental imagery classes, each session 30 minute, twice a week and for 8 weeks. The blood pressures will be measured before and after the intervention

**Category**

Treatment - Other

**2****Description**

Intervention: In control group the blood pressures will be measured twice a week, before and after a 15-min rest

**Category**

Treatment - Other

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

Kosar hospital

**Full name of responsible person**

Fatemeh Ranjkesh

**Street address****City**

Qazvin

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Investigator

**Full name of responsible person**

Fatemeh Ranjkesh

**Street address**

Bahonar Boulevard, Qazvin University of Medical Sciences, Vice chancellor for research

**City**

Qazvin

**Grant name**

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Investigator

**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**

Qzvin University of Medical Sciences

**Full name of responsible person**

Fatemeh Ranjkesh

**Position**

Instructor, Msc in midwifery

**Other areas of specialty/work**

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## Person responsible for updating data

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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*