

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of auriculotherapy on pregnancy hypertension in pregnant women

#### Protocol summary

##### Study aim

Determination Effect of Ear Acupressure on Pregnancy Hypertension in Pregnant Women Referring to Qazvin Kosar Medical Center

##### Design

This study is a randomized, controlled clinical trial. Available sampling method 80 pregnant mothers with high blood pressure. The conditions of entry into the study are divided into four interventional and control groups.

##### Settings and conduct

In the intervention group, in addition to receiving the usual medical care of the hospital, for acupressure patients, the ear will be labeled with 6 seeds on the back of the ear for eight sessions, and the mothers press seeds 6 times a day for 1 minute to reach the threshold of pain, and twice a week to replace the seeds and control blood pressure. Each mother, 8 sessions, and each ear, 4 times., and their blood pressure will be measured and recorded at each visit after 15 minutes of rest.

##### Participants/Inclusion and exclusion criteria

entering Criteria Pregnant women 32-20 weeks; Hypertension 140/140 mmHg and higher without proteinuria; Singleton pregnancy; Having reading and writing; Not having external ear disease. Exit criteria Pre-eclampsia, eclampsia and Hellp syndrome; Systolic blood pressure equal to 160 mm Hg; Diastolic blood pressure equal t or greater than 110 mmHg; Having chronic diseases (diabetes, cardiovascular diseases, chronic blood pressure, etc.); Having uterine contractions and vaginal bleeding; Use of psychoactive substances and cigarettes and alcohol; use of other methods of complementary medicine.

##### Intervention groups

40 patients in the intervention group and performing the intervention protocol in addition to the usual medical care for four weeks and control of blood pressure twice a week 40 patients in the control group and performing

usual medical care for four weeks and control of blood pressure twice a week

##### Main outcome variables

Reduce blood pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190402043156N1**

Registration date: **2019-05-01, 1398/02/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-05-01, 1398/02/11**

Update count: **0**

##### Registration date

2019-05-01, 1398/02/11

##### Registrant information

##### Name

Ladan Keshtkar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3335 7946

##### Email address

l.keshtkar@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2019-09-22, 1398/06/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of auriculotherapy on pregnancy hypertension in pregnant women

**Public title**

The effect of auriculotherapy on pregnancy hypertension in pregnant women

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

1. Pregnant women 32-20 weeks;2. Hypertension 140/140 mmHg and higher without proteinuria;3. Single pregnancy;4. Having reading and writing;5. Not having external ear disease. 2. Hypertension 140/140 mmHg and higher without proteinuria 3. Singleton pregnancy 4. Having reading and writing 5. Not having external ear disease

**Exclusion criteria:****Age**

From **18 years** old to **49 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For random assignment Considering that we have two therapies (acupuncture and conventional medical care), we will use the 4th block. There are six different modes for the four blocks: (Aaaa, aaAA, AaAa.aAaA, AaAA, AaAa.aAaA, AaaA, aAAa), different states are written on six cards and will be dropped inside a bag. By selecting 20 blocks of six blocks, the allocation process of 80 patients to the two groups before The study will be started.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients in both groups and clinic nurses will not be informed of the groups

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

ethics committee of Qazvin univercity of medical sciences

**Street address**

Shahid Bahonar Blvd. - Qazvin University of Medical Sciences

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3613645569

**Approval date**

2019-02-27, 1397/12/08

**Ethics committee reference number**

IR.QUMS.REC.1397.370

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

Pregnancy Hypertension

**ICD-10 code**

O10-O16

**ICD-10 code description**

Oedema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium

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

blood pressure

**Timepoint**

twice in a week for four weeks

**Method of measurement**

The arterial artery pressure in each session is measured by a mercuric barometric device (ABN) made in the country of Germany, calibrated every six months. In all cases, measurements will be made from the right arm and in the sitting position

**Secondary outcomes**

empty

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

Intervention group: In the intervention group, in addition to receiving the usual medical care of the hospital, the acupressure acupressure of the ears will be carried out by the researcher in the form of a label with 6 seeds of

Seid (to completely cover the line of hypertension) on the hypertension line behind the ear during 8 sessions and will ask the mother Take 6 times at least 1 minute on squeezed seeds to reach the threshold of pain, and twice a week to replace the seizable labels and control blood pressure. Each mother, 8 sessions, and each ear, 4 times the adhesives are replaced, and their blood pressure will be measured and recorded at each visit for changing the adhesive containing seeds after 15 minutes of rest.

**Category**

Treatment - Other

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

Kowsar Medical Center

**Full name of responsible person**

Ladan Keshtkar

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Taleghani Ave.Kowsar Medical Center

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itkosar@qums.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

دکتر امیر پیمانی

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

Yes

**Title of funding source**

Qazvin University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Ladan Keshtkar

**Position**

nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

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**Position**

nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Ladan Keshtkar  
**Position**  
nurse  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

The results of the data will be published as a article

### When the data will become available and for how long

" the Access Period since 1399"

### To whom data/document is available

Only for researchers working in academic and scientific institutions

### Under which criteria data/document could be used

reserch

### From where data/document is obtainable

l.keshtkar@qums.ac.ir

### What processes are involved for a request to access data/document

By sending an email after the end of study 1399

### Comments