Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Street address

Taleghani Ave.Kowsar Medical Center

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Qazvin

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Email

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

Street address

Shahid Bahonar Blvd. Ghazvin University of Medical Sciences

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Phone

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Email

Info@qums.ac.ir

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

Taleqani Ave. Kowsar Medical Center

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Email

l.keshtkar@qums.ac.ir

Person responsible for scientific 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 updating data

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
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l.keshtkar@qums.ac.ir

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