Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Auriculotherapy on cervical ripening, initition and outcome of labor in term primiparous women

Protocol summary

Study aim
The effect of Auriculotherapy on cervical ripening, initition and outcome of labor in term primiparous women.

Design
A randomized, double-blind, placebo-controlled clinical trial.

Settings and conduct
A single-blind randomized clinical trial study on 70 mothers with first pregnancy between 39 and 40 weeks, under Qom University of Medical Sciences and met the inclusion criteria, Done.Mothers are included in the study continuously and by block- method in both randomly assigned.The demographic and midwifery questionnaire is completed by the researcher.In case of bishop less than 4, enter the study and auriculotherapy is performed in the intervention group.If the uterine contractions do not start effectively or the cervix is ready for auriculotherapy again.For blinding, in the placebo group, auriculotherapy is performed falsely and is followed after 72 hours.If both groups need to be hospitalized for any reason, reaching 40 full weeks or not starting uterine contractions after 144 hours, they will be referred to the hospital and if hospitalized until the end of labor, the researcher will follow up.

Participants/Inclusion and exclusion criteria
Primiparous؛ Gestational age 39 to 40 weeks؛ Pregnancy is low risk,18-35 years؛ Cephalic presentation؛ Bishop score less than 4؛ Lack of stenosis of the pelvis؛ No use of any complementary or traditional method for induction of labor؛ Lack of uterine contractions؛ Ears Without Problems

Intervention groups
test group, the intervention placed on the 5 points of the right and left ear of the seed and Pressing the seeds every 1 hour per day, and this continues for up to 72 hours. In the absence of cervical ripening and labor initiation, auriculotherapy re-done. In the placebo group, auriculotherapy is done artificially and without Vakarya seeds embedded on 3 points and not pressing.

Main outcome variables
cervical ripening, initition and outcome of labor.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190226042845N1**
Registration date: **2020-04-21, 1399/02/02**
Registration timing: **retrospective**

Last update: **2020-04-21, 1399/02/02**
Update count: **0**

Registration date
2020-04-21, 1399/02/02

Registrant information

Name
Zeynab Mozafarirad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3289 4431

Email address
z-mozafarirad@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-10-22, 1398/07/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Auriculotherapy on cervical ripening, initition and outcome of labor in term primiparous women

Public title

The effect of acupressure on the onset of labor pain and its outcome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: All pregnant women with gestational age of 39 weeks to 40 weeks Primiparous Age 18-35 Years Pregnancy is low risk (Lack of any known internal and surgical disease and complications associated with pregnancy) Fetus with cephalic presentation Bishop Cervical Score Less than 4 before the study Single pregnancy Index Body mass 19.8 to 30 Estimated fetal weight less than 4000 grams Healthy amniotic sac (Also lack of oligo and poly hydramnios) Lack of stenosis of the pelvis Lack of sex 72 hours before the study No use of any complementary or traditional method for induction of labor Lack of uterine contractions External ear on both sides with no lumps, swelling, infection or wound for auriculotherapy

Exclusion criteria:

Breech presentation High risk pregnancy such as gestational diabetes, high blood pressure in pregnancy, Previa Estimated fetal weight over 4000 grams Bleeding before and during the study Stripping before starting the study Decrease fetal movement Use of any complementary or traditional method for induction of labor Nipple stimulation during study Rupture of the amniotic sac before the start of the study No pressure points in 1full day Cancellation and dissatisfaction with the mother of auriculotherapy Request termination of pregnancy by elective cesarean section or pharmaceutical methods

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Researchers referred to counseling centers, midwifery and health centers Society of Medical Sciences Qom after introducing his plan, sufficient information on the research, such as research, study objectives, criteria for inclusion and exclusion criteria, how to how to conduct the study in pregnant women explained. Individuals willing to participate in the research and have criteria for entering the study are referred to the researcher and are informed by the informed consent and informed by a continuous and available sampling method.The samples were then randomly assigned (Permuted-Block Randomization) to two intervention and placebo groups as follows. That all possibilities for placement of the letters A and B will be considered in four blocks that make up a total of 6 modes. The 6 modes are numbered 1 to 6 and the number of 4 blocks required will be determined based on the number of sample cases. Then the required number of blocks, random number based on random numbers table will burst row, the top 6 numbers will not be considered. Finally, based on the order of the numbers extracted from the table, the blocks for each number will be listed, respectively, and when each instance is entered into the study, each person will take a specific word in order. For example, in the order of (AABB / AABB), the 5th person will be in Group B.Randomly, half the people of each block are placed in one group and the other half in the other group. In this study, we want to place 90 people in two groups of 45 patients in the field of auriculotherapy and placebo.

Blinding (investigator's opinion)

Single blinded

Blinding description

A placebo group has been identified to achieve the goal of blindness. In the placebo group, the procedure will be performed in such a way that the outer ear is cleansed ,Then several points from the same points in the intervention group that are effective for induction of childbirth are artificially Massage with a pointer machine, so that no stimulation is performed.Then on the 3rd point of the left ear and on the 3rd point of the right ear, there is a seed placed without vakaria.The pregnant mother is told not to press the points.The placebo group 72 hours after vaginal examination done to determine the Bishop score, also uterine contractions and fetal heart rate also examined. The placebo group is also evaluated from the time of admission to the completion of the delivery stages.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Organizational Ethics Committee for Research in School of Nursing and Midwifery and School of Rehabi

Street address

Tehran University of Medical Sciences, Tehran, Tohid

Square, Dr. Mirkhani St. (East Nursing)

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2019-02-02, 1397/11/13

Ethics committee reference number
IR.TUMS.FNM.REC.1397.194

Health conditions studied

1

Description of health condition studied
cervical ripening and labor initiation

ICD-10 code
080.0

ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
Cervical ripening

Timepoint
Before intervention, 72 and 144 hours after intervention and hospitalization time

Method of measurement
Vaginal examination

2

Description
Initiation labour

Timepoint
Before intervention, 72 and 144 hours after intervention and hospitalization time

Method of measurement
examination

Secondary outcomes

1

Description
The length of the first stage of labor

Timepoint
The end of the study

Method of measurement
Researcher-made questionnaire

2

Description
The length of the second stage of labor

Timepoint
The end of the study

Method of measurement
Researcher-made questionnaire

3

Description
Baby Apgar

Timepoint
The end of the study

Method of measurement
Researcher-made questionnaire

4

Description
Type of delivery

Timepoint
The end of the study

Method of measurement
Researcher-made questionnaire

5

Description
Use of Oxytocin

Timepoint
The end of the study

Method of measurement
Researcher-made questionnaire

Intervention groups

1

Description
Intervention group: We randomly place 70 regnant women in the intervention and placebo groups. For each individual intervention group explained that auriculotherapy from 39 weeks to 40 weeks of pregnancy once done. If the cervix is unprepared and the labor pains do not begin 72 hours after the intervention, auriculotherapy is performed again. In the intervention group, before auriculotherapy to determine the Bishop score, vaginal exam as well as uterine contractions and fetal heart checked. For the preparation of cervix and the onset of labour, 11 points are stimulated: Shen Men, master shoulder , thalamic, Hypothalamus, prostaglandin, anterior pituitary, posterior pituitary, endocrine, (2) uterine, lumbar and lung. After disinfection of the ear with 75% alcohol and one minute of general massage for relaxation, electrical stimulation was performed with a Pointer Excel 2 (Made in China) device with a frequency of 2–4 Hz and a current intensity of 2–4 mA, each point is stimulated by the researcher for 15 seconds. . Finally, 5 points of left ear including endocrine, posterior pituitary, prostaglandin and uterus (2 points) and 5 points of right ear including Shen Men ,thalamic, master shoulder ,lung, lumbar are placed one vacaria seed. The mother is instructed to push each point up to 72 hours every hour for 1 minute. Seed pressure should be enough power to cause pain and irritation of the outer ear.They may also experience different sensations when seed pressure, such as

numbness, swelling, mild pain or heat. It should be noted that during sleep and rest for 8 hours do not need to squeeze. To prevent forgetfulness, the researcher remembers pressing the points by phone, asking for possible problems and complications.

Category

Treatment - Other

2

Description

Placebo group: The placebo group will consist of 35 pregnant women who are eligible for the study. In this group, the outer ear is cleaned with 75% alcohol and then several points from the same points in the intervention group are massaged with the silent machine so that the stimulation is not triggered. It is then placed on the 3 points of the left ear including the thalamic, Shen Men, lung and the 3 points of the right ear including the posterior pituitary, prostaglandin and the uterus of a seed without vakaria. The pregnant mother is told not to push the points at all.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Qom University of Medical Sciences

Full name of responsible person
Zeynab Mozafari Rad

Street address
Qom University of Medical Sciences,St. Shahid Lavasani , Qom

City
Qom

Province
Ghoum

Postal code
3713649373

Phone
+98 25 3770 6470

Email
z.mozafarirad.midwif@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Esmat Karimi

Street address
No. 23, Damascus Ave., Valiasr Ave., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 6105 4222

Email
khakbaza@sina.tums.ac.ir

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

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
Tehran University of Medical Sciences

Full name of responsible person
Zeynab Mozafari Rad

Position
Graduate student of Midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
College of Nursing and Midwifery, Tehran University of Medical Sciences, Tohid Square, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 6692 7171

Email
z.mozafarirad.midwif@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Zohreh Khakbazan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Tohid Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Email

khakbaza@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zeynab Mozafari Rad

Position

Graduate student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

College of Nursing and Midwifery, Tehran University of Medical Sciences, Tohid Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Email

z.mozafarirad.midwif@gmail.com

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

Only part of the data, such as information about the original outcome or the like, can be shared

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Data can be obtained by researchers and people who are in treatment.

Under which criteria data/document could be used

Data can be obtained by researchers and people who are in treatment.

From where data/document is obtainable

z.mozafarirad.midwif@gmail.com

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

z.mozafarirad.midwif@gmail.com

Comments