Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of uriculotherapy on the level of labor anxiety in primiparous women

Protocol summary

Study aim

The effect of uriculotherapy on the level of labor anxiety in primiparous women referred to Qom University of Medical Sciences.

Design

In the intervention group an Uriculotherapy technique was used by a researcher when mother had no pain in dilatation of 6 and 8 cm, in the ears of the ears on the masterpinette (Zero, Gray Man, Endocrine, Thalamic Point), Pituitary gonadotropin points, uterine regions, prostaglandin points, external genital points using the pointerplus2 device. The investigator for each patient with a Pointer Plus device for 30 seconds Presses the points in both ears at intervals of 1 hour.

Settings and conduct

166 women admitted to labor of the selected hospitals under the supervision of Qom University of Medical Sciences were randomly divided into two groups of uriculotherapy intervention. and control

Participants/Inclusion and exclusion criteria

Sample entry criteria: Primiparous with low risk pregnancy, Gestational age - 40 37 weeks, Cephalic presentation, Single pregnancy, Age between 18-35 years, 4/26 > BMI > 8/19, Minimum literacy skills, at least one healthy ear, healthy water bag, Mild anxiety (20-40 score according to Spielberger questionnaire). Exclusion criteria: taking pain medication within 3 hours before and during the study, Drug addiction, Being an athlete, History of infertility, Illiteracy, Underlying disease associated with the auditory and ear canals, Medical disorder during pregnancy, Visit the center with a torn water bag, Dissatisfaction with continuing the study.

Intervention groups

In the present study the intervention was Uriculotherapy and in the control group, Clients do not receive any sedation or special techniques during labor and delivery.

Main outcome variables

Maternal anxiety, Postpartum Depression

General information

Reason for update

Hi Respectfully, a slight change in the title is considered by the researcher, because due to the difficulty of definitive follow-up, depression and refusal of the research units to go to the hospital and increase the sampling time due to the current corona atmosphere in the center treatment is needed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20121230011944N4**
Registration date: **2020-07-13, 1399/04/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-21, 1399/07/30**
Update count: **2**

Registration date

2020-07-13, 1399/04/23

Registrant information

Name
Mehrnoush Ghaemmaghami
Name of organization / entity
Faculty of Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 86 3417 3502
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-15, 1397/12/24

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

2019-03-15, 1397/12/24

Actual recruitment end date

2020-09-05, 1399/06/15

Trial completion date

2020-09-05, 1399/06/15

Scientific title

The effect of uriculotherapy on the level of labor anxiety in primiparous women

Public title

The effect of uriculotherapy on the level of labor anxiety in primiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous women Containing low-risk pregnancy Gestational age 40-37 weeks Cephalic presentation Single pregnancy Age between 18-35 years 4/26> BMI> 8/19 Minimum literacy skills Having at least one healthy ear Has a healthy gestational sac Mild anxiety (20-40 score according to Spielberger questionnaire)

Exclusion criteria:

taking pain medication within 3 hours before and during the study Drug addiction Being an athlete History of infertility Illiteracy Underlying disease associated with the auditory and ear canals Medical disorder during pregnancy Visit the center with a torn water bag Dissatisfaction with continuing the study

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **166**

Actual sample size reached: **166**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Clinical trial, control group, non-blind, randomized

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Research Deputy, Supreme Prophet (pbuh) complex, Basij Square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

Approval date

2018-07-18, 1397/04/27

Ethics committee reference number

IR.ARAKMU.REC.1397.144

Health conditions studied

1

Description of health condition studied

Levels of labor anxiety in primiparous women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The Anxiety in primiparous women

Timepoint

Before intervention, after intervention

Method of measurement

Speilberger Anxiety Inventory

Secondary outcomes

1

Description

The Depression in primiparous women

Timepoint

Before intervention, after intervention

Method of measurement

Beck Depression Inventory II

2

Description

The Anxiety in primiparous women

Timepoint

Before intervention, after intervention

Method of measurement

Speilberger Anxiety Inventory

Intervention groups

1

Description
Intervention group: Uricholotherapy Intervention group: In the intervention group an Uricholotherapy technique was used by a researcher whose mother was in pain and had no pain, and the first time after 4 hours, which did not develop after an hour, and then at dilatation of 6 and 8 cm, in the ears of the ears on the masterpinette (2 points), uterine points (3 dots), prostaglandin points (2 dots), genital outer points (2 dots) using a pointer plate of Excel (2), pituitary gland (2 points) (Made in China). For every patient with a Pointer Plus device for 30 seconds, the listed points In both ears, it presses every 1 hour.

Category
Treatment - Other

2

Description
Control group: Clients do not receive any special sedation or techniques during labor and delivery.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Selected Hospitals under the Supervision of Qom Medical Sciences University

Full name of responsible person
Narges sheikhghanbari

Street address
Qom University of Medical Sciences, Saheli Street, Qom

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Web page address
https://arakmu.ac.ir/vcr/fa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr. Alireza Kamali

Street address
A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

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research@arakmu.ac.ir

Web page address
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Mehrnoush Ghaemmaghami

Position
Faculty Member of Medicine School

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Publish document as article

When the data will become available and for how long

Between the next 12 - 18 months

To whom data/document is available

All people

Under which criteria data/document could be used

Notices

From where data/document is obtainable

magazines

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

online

Comments