

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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)

##### Phone

+98 86 3417 3502

##### Email address

mehrnoushghmghm68@yahoo.com

##### 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

#### City

Qom

#### Province

Ghous

#### Postal code

3716889788

#### Phone

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+98 86 3313 3147

#### Email

Mehrnoushghmghm68@yahoo.com

#### 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

#### City

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3848176341

#### Phone

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#### Email

research@arakmu.ac.ir

#### Web page address

<https://arakmu.ac.ir/vcr/fa>

### 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

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**Latest degree**

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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**