

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### evaluation of the effect of nipple stimulation in pregnant women admitted with labor pain in latent phase

#### Protocol summary

##### Study aim

Comparison of duration of latent and active phase of labor in women with and without nipple stimulation.

##### Design

randomization method is block randomization. the midwife who admits the patient writes the number in admit sheet and being in case or control group is determined with the resident.

##### Settings and conduct

the study will take place in Alzahra and Taleghani hospital of Tabriz

##### Participants/Inclusion and exclusion criteria

Term pregnant women with labor pain and cervical dilatation less than 3 centimeters.

##### Intervention groups

pregnant women in case group do nipple stimulation when they do not have uterine contraction , each stimulation lasts 3- minute and stimulates nipples intermittently

##### Main outcome variables

duration of active phase; duration of latent phase

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190304042912N1**

Registration date: **2019-07-13, 1398/04/22**

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

Last update: **2019-07-13, 1398/04/22**

Update count: **0**

##### Registration date

2019-07-13, 1398/04/22

##### Registrant information

##### Name

sanaz moosavi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3553 9161

##### Email address

musevis@tbzmed.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-07-06, 1398/04/15

##### Expected recruitment end date

2019-08-22, 1398/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

evaluation of the effect of nipple stimulation in pregnant women admitted with labor pain in latent phase

##### Public title

evaluation of the effect of nipple stimulation in pregnant women admitted with labor pain in latent phase

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

pregnant term with labor pain cervical dilatation less than 3 cm

##### Exclusion criteria:

previous cesarean preeclampsia chorioamnionitis multifetal gestation macrosom fetus iugr fetus polyhydramnios

##### Age

From **16 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **95**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

block randomization

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Evaluator of outcome and person who analyses are blind of intervention and group of patients.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

ethics committee of tabriz university of medical sciences

**Street address**

Tabriz university of medical sciences, golgasht Ave, Tabriz , Iran

**City**

tabriz

**Province**

East Azarbaijan

**Postal code**

5157815343

**Approval date**

2019-06-05, 1398/03/15

**Ethics committee reference number**

5/62/2743/3

2

**Ethics committee**

**Name of ethics committee**

ethics committee of department of obstetrics and gynecology in tabriz

**Street address**

Alzahra hospital, Artesh Ave, Tabriz , Iran

**City**

tabriz

**Province**

East Azarbaijan

**Postal code**

5157815343

**Approval date**

2019-03-01, 1397/12/10

**Ethics committee reference number**

5622743

**Health conditions studied**

1

**Description of health condition studied**

duration of labor

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

duration of latent phase

**Timepoint**

after intervention and delivery

**Method of measurement**

patient chart

**Secondary outcomes**

1

**Description**

duration of acute phase of labor

**Timepoint**

after intervention and delivery

**Method of measurement**

patient chart

**Intervention groups**

1

**Description**

Intervention group: nipple stimulation

**Category**

Treatment - Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Alzahra hospital, Taleghani hospital

**Full name of responsible person**

SANAZ MOUSAVI

**Street address**

Alzahra hospital, Artesh Ave.

**City**

tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5157815343  
**Phone**  
+98 41 3554 1221  
**Email**  
moosavisanz@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
SANAZ MOUSAVI  
**Street address**  
ALZAHRA hospital, Artesh Ave  
**City**  
tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5157815343  
**Phone**  
+98 41 3331 5372  
**Email**  
moosavisanz@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Tabriz 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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
SANAZ MOUSAVI  
**Position**  
assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**

Gynecology and Obstetrics  
**Street address**  
Alzahra hospital- Artesh Ave.  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5157815343  
**Phone**  
+98 984135541221  
**Email**  
moosavisanz@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
SANAZ MOUSAVI  
**Position**  
assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
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5157815343  
**Phone**  
+98 41 3554 1221  
**Email**  
moosavisanz@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
SANAZ MOUSAVI  
**Position**  
assistant professor  
**Latest degree**  
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**Postal code**  
5157815343

**Phone**

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**Email**

moosavisanaz@yahoo.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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**

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

**Analytic Code**

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

**Data Dictionary**

Not applicable