

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of honey syrup, honey syrup and birth ball, honey syrup and birth ball and hearing the sound of nature for decreasing the labor pain in nulliparous women.

Protocol summary

Summary

The objective of the study is to compare the effect of three combined interventions for pleasant the active phase of labour in nulliparous women. In this study, for 128 pregnant women in Lolagar hospital , a pain questionnaire will be completed through interviews .by completing the consent form , they will be entered into the study. Inclusion criteria's are: age 20-35 years, 38-42 weeks gestational age, presence of cephalic presentation, has physical and mental health, Not being infertile, having a normal vaginal delivery , 4-5 cm Dilatation of cervix, less than 6 hours PROM, no history of allergy to honey, not fear of hearing the sounds of nature (sound waves, sea, water ...) exclusion criteria: mothers who do not cooperate , not having the natural course of labor due to maternal complications , placental or fetal factors, over six hours PROM, induce labor with oxytocin, use honey syrup less than 150 cc, absence of the intervention process less than 30 minutes. The samples were randomly divided into four experimental and control groups (32 in each group). After the intervention (including honey syrup, use of birth ball, both methods together) pain intensity score will be assessed. then the results will be compared to previous results .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611042172N20**

Registration date: **2017-01-05, 1395/10/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-05, 1395/10/16

Registrant information

Name

Simin Taavoni

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Iran University of medical Science

Expected recruitment start date

2016-12-30, 1395/10/10

Expected recruitment end date

2017-05-31, 1396/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of honey syrup, honey syrup and birth ball, honey syrup and birth ball and hearing the sound of nature for decreasing the labor pain in nulliparous women.

Public title

Comparison the effect of three combined interventions for pleasant the active phase of labour in nuliparous

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria included: age 20-35 years, 38-42 weeks gestational age, presence of cephalic presentation, has physical and mental health, Not having infertility, having a vaginal delivery and physiologic conditions, 4-5 cm Dilatation of cervix, less than 6 hours PROM, no history of allergy to honey, no fear of hearing the sounds of nature (sound waves, sea, water ...) exclusion criteria: lack of cooperation , not having natural course of labor due to maternal complications , placental or fetal factors, over six hours PROM, induce labor with oxytocin, use honey syrup less than 150 cc, absence of the intervention process less than 30 minutes.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Science

Street address

Faculty of Nursing and Midwifery, Shahid yasemi street, Valiasr street

City

Tehran

Postal code**Approval date**

2016-12-11, 1395/09/21

Ethics committee reference number

IR.IUMS.REC 1395.9311373010

Health conditions studied**1****Description of health condition studied**

Active phase of labor pain

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes**1****Description**

Pain intensity of active phase of labor

Timepoint

On arrival and then every 30 minutes up to eight centimeters dilatation

Method of measurement

Pain ruler

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group consumed two and a half teaspoons of honey syrup in 150 ml of water and Rotate hips to the left and right and front and rear by research support.

Category

N/A

2**Description**

In the second group intervention, In addition to the consumption of honey syrup, acting especially pelvic movements using the birth ball and hearing the sound of nature

Category

N/A

3**Description**

In the third intervention group, in addition to maintaining the intervention group 2, only special moves pelvic conditions on the birth ball will be supported by researchers

Category

N/A

4**Description**

control group receive Routine hospital care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Lalagar Hospital

Full name of responsible person

Foorozan Kamyani

Street address

South Khosh Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Dr Nahid Akbary

Street address

Faculty of Nursing and Midwifery, Rashid yasemi Street, Valiasr street

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Nursing and Midwifery Faculty, Iran University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty