Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 corporate , 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

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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 pleasuent 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 dilatasion

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 groop, 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 recive 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

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Person responsible for updating data

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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