Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of using the lubricant gel during the active phase of the first stage of the labor on the length of delivery and perineal trauma in primiparous women.

Protocol summary

Study aim
The effect of lubricant gel during the first phase of labor on labor stages and perineal health.
Design
Randomization will be done using a random number table.The sample size will be 55 in each group.The clinical trial will include a control group.
Settings and conduct
The research will be about the use of the Lubricant Gel.The site of this clinical trial will be Maternity ward at Iran Hospital affiliated by Iranshahr University of Medical Sciences.Blindness will only be for data analytics.
Participants/Inclusion and exclusion criteria
Inclusion Criteria: mother age will be 18-35 years old; Single pregnancy; Cephalic presentation; being at gestational age of 42-37 weeks. Exclusion criteria: rupture of amniotic membrane; Suspected of embryonic anomalies; Suspected of cephalopelvic disproportion; Maternal diseases; History of surgery on the uterus; Twin pregnancy; Preterm labor.
Intervention groups
In the experimental group, 5 ml of water-soluble lubricant gel is used at each vaginal examination.In the control group, routine actions are performed.
Main outcome variables
Length of delivery stage; Perineum status

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160418027464N2**
Registration date: **2019-03-12, 1397/12/21**
Registration timing: **prospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **1**
Registration date
2019-03-12, 1397/12/21

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 37212968054
Email address
dr.azarkish@irshums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-03-14, 1397/12/23
Expected recruitment end date
2019-05-22, 1398/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of using the lubricant gel during the active phase of the first stage of the labor on the length of delivery and perineal trauma in primiparous women.

Public title
Effect of Lubricant gel on labor consequences.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:

Primary Porous Single pregnancy Cephalic Presentation - Gestational Age 42-37 weeks Active phase of labor.
Exclusion criteria:
Symptoms of Amniotic fluid Infection Symptoms of Respiratory Distress Long-term rupture of amniotic fluid Fetal abnormality Cephalopelvic Disproportion Surgery on uterus Preterm pregnancy

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

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
A sealed package containing dedicated interventions will be created based on a randomization list for each patient.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyzer will not be aware of the data codes.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iranshahr University of Medical Sciences

Street address
Balouch Street

City
Iranshahr

Province
Sistan-va-Balouchestan

Postal code
۹۹۱۶۶۴۳۵۳۵

Approval date
2016-02-29, 1394/12/10

Ethics committee reference number
IR.IRSHUMS.REC.1394.9

Health conditions studied

1

Description of health condition studied
outcome of delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The length of the first stage of labor

Timepoint
Determine the length of delivery stages after intervention

Method of measurement
Clock

2

Description
Perineum status

Timepoint
The examination of the condition of the perineum will be performed after the end of the third stage of labor.

Method of measurement
Investigating the condition of the perinea by the researcher.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, from the time of the 4 cm dilatation of the cervix to the second stage of delivery, 5 ml of water-soluble Lubricant gel produced by Shafa company will be used at each vaginal examination.

Category
Treatment - Other

2

Description
Control group: In the control group, routine care will be provided.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Maternity hospital of Iran, Iranshahr
Full name of responsible person
Fatemeh Azarkish
Street address
Education and Research Management part, Deputy Director of Education and Research, Balouch street
City
Iranshahr
Province
Sistan-va-Balouchestan
Postal code
۷۶۱۸۸۱۵۶۷۶
Phone
+98 54 3721 3328
Fax
+98 54 3721 3328
Email
Azarkish2005@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranshahr University of Medical Sciences
Full name of responsible person
Dr Fatemeh Azarkish
Street address
Education Management part, Baloch Street, Iranshahr.
City
Iranshahr
Province
Sistan-va-Balouchestan
Postal code
۷۶۱۸۸۱۵۶۷۶
Phone
+98 54 3721 0485
Fax
+98 54 3721 0485
Email
tahminehsalehian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iranshahr 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
Iranshahr University of Medical Sciences
Full name of responsible person
Fatemeh Azarkish
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Balouch
City
Iranshahr
Province
Sistan-va-Balouchestan
Postal code
۷۶۱۸۸۱۵۶۷۶
Phone
+98 37210485
Fax
Email
Azarkish2005@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iranshahr University of Medical Sciences
Full name of responsible person
Fatemeh Azarkish
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Balouch
City
Iranshahr
Province
Sistan-va-Balouchestan
Postal code
۷۶۱۸۸۱۵۶۷۶
Phone
+98 54 3721 3328
Fax
+98 54 3721 3328
Email
Azarkish2005@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Iranshahr University of Medical Sciences
Full name of responsible person

Fatemeh Azarkish
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Balouch
City
Iranshahr
Province
Sistan-va-Balouchestan
Postal code
۷۶۱۸۸۱۵۶۷۶
Phone
+98 54 3721 3328
Fax
+98 54 3721 3328
Email
Azarkish2005@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Sharing will be in the form of the article.
When the data will become available and for how long
One year after the end of the plan.
To whom data/document is available
Only available to scholars working in academic and academic institutions.
Under which criteria data/document could be used
It will be possible to use the data by sending the email to the responsible author.
From where data/document is obtainable
Corresponding to the author of the article.
What processes are involved for a request to access data/document
After sending the email to the responsible author, it will be answered within a week.
Comments
Use of data will only be possible in academic approved schemes.