Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effects of dextrose saline compared to normal saline on the duration of active phase of labor in nulliparous women

Protocol summary

Study aim
Determining the effect of saline dextrose solution compared with normal saline on the duration of the active delivery phase in Noli Par women

Design
Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 0 on 60 patients. The table of random numbers was used for randomization.

Settings and conduct
This clinical trial study will be performed on Noli Par women visiting Imam Reza, Ghaem and Umm Al-Banin hospitals.

Participants/Inclusion and exclusion criteria
Inclusion criteria :Noli Par women, age between 18 to 40 years old Exclusion criteria: Dissatisfaction with participation in the study, having underlying disease

Intervention groups
In the intervention group, saline dextrose solution (5% dextrose and 0.9% sodium chloride) is infused by pump to the mother. (150 cc per hour)

Main outcome variables
71/5000 The duration of the active phase of labor (from 5 cm dilatation to complete dilatation)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200620047838N1**
Registration date: **2020-08-24, 1399/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-24, 1399/06/03**
Update count: **0**

Registration date
2020-08-24, 1399/06/03

Registrant information

Name
Seyedeh Sepideh Hoseini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3802 2631

Email address
sepidehh787@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effects of dextrose saline compared to normal saline on the duration of active phase of labor in nulliparous women

Public title
Evaluation the effects of dextrose saline compared to normal saline on the duration of active phase of labor in nulliparous women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnancy age between 37 and 40 weeks Single pregnancy Ceramic perforation Cervical dilatation 5 cm

Exclusion criteria:

pregnant who fetuses have intrauterine growth restriction BMI is more than 40 Poly hydramnios People with diabetes and preeclampsia Kidney patients existence of active infection in the mother Maternal heart disease

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done with a table of random numbers. In this way, the computer generates random numbers between 0 and 1. If the random number is less than 0.500, the person will enter the intervention group. If the random number is greater than 0.500, the person enters the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participations and çareprovuder do not know who is in which group. Individuals were identified as groups A and B so that the statistician was unaware of the type of drug and the patients themselves were unaware of the drug being injected.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Department of Obstetrics and Gynecology, Imam Reza Hospital, Taghiabad Square

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۳۷۹۱۳۳۱۶

Approval date
2020-04-29, 1399/02/10

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.061

Health conditions studied

1

Description of health condition studied
Long labour

ICD-10 code
O63

ICD-10 code description
Long labor

Primary outcomes

1

Description
The duration of the active phase of labor (from 5 cm dilatation to complete dilatation)

Timepoint
after intervention

Method of measurement
5 cm dilatation to complete dilatation

Secondary outcomes

1

Description
The length of the second stage of labor (from complete dilatation to the birth of the baby)

Timepoint
after intervantion

Method of measurement
complete dilatation to the birth of the baby

Intervention groups

1

Description
Intervention group: In the intervention group, dextrose saline solution solution (5% dextrose and 0.9% sodium chloride) is infused by pump to the mother. (150 cc per hour)

Category
Other

2

Description
Control group: In the control group, normal saline solution with pump device to regulate the drops, noli Par women in the active phase of childbirth are prescribed.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Sepideh Hoseini

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Department of Obstetrics and Gynecology, Imam Reza Hospital, Taghiabad Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Seyedeh Sepideh Hosseini

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Department of Obstetrics and Gynecology, Imam Reza Hospital, Taghiabad Square

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data as SPSS file
When the data will become available and for how long
After publishing of the article
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
It is permissible to compare our data by studying others by citing the source on the delivered data
From where data/document is obtainable
Send an email to Dr.Sepideh.hosseini@gmail.com
What processes are involved for a request to access data/document
After sending an email and justifying the author about not using the data, the data is sent to the researcher.
Comments