

# 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)

##### Phone

+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 careprovuder 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

9137913316

#### 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 (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

**Street address**

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

**City**

Mashhad

**Province**

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**Postal code**

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**Phone**

+98 51 3802 2632

**Email**

Dr.Sepideh.hosseini@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

International Offic Administration Center(Qoreishi Building) ; Daneshgah St.,

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3841 2081

**Email**

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

**Street address**

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

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## Person responsible for scientific 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

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## Person responsible for updating data

#### Contact

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Mashhad University of Medical Sciences

**Full name of responsible person**

Seyedeh Sepideh Hosseini

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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**