

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The effect of topical magnesium sulfate on cervical edema in women admitted to childbirth ward of Imam Khomeini Hospital of Divandareh in 2019.

#### Protocol summary

##### Study aim

Determine the effect of topical magnesium sulfate on cervical edema in women admitted to childbirth ward of Imam Khomeini Hospital of Divandareh in 2019.

##### Design

Randomized clinical trial

##### Settings and conduct

Maternity ward of Imam Khomeini hospital in Divandareh city In the intervention group, 10% magnesium sulfate 10 cc will be topically applied to the cervix by the researcher through a 10 cc syringe. And if the cervical swelling does not improve after two hours, 10 cc of magnesium sulfate will be poured again on the cervix. The control group will receive 10 cc normal saline under the same conditions

##### Participants/Inclusion and exclusion criteria

Inclusion: Age 18-35 years, Primiparous, Gestational age 37-42, Cephalic presentation, Singleton, BMI 19.8-30, NST reactive, Willingness to participate in the study, History of severe dysmenorrhea, History of infertility, Narcotic use during pregnancy, Attend birth statistics classes Exclusion: There are indications for cesarean section, Maternal withdrawal from continuing study

##### Intervention groups

In the intervention group, 50% magnesium sulfate vial will be applied topically to the cervix using a syringe. The control group will receive normal saline as placebo.

##### Main outcome variables

Improve cervical edema

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171210037807N2**  
Registration date: **2019-12-12, 1398/09/21**

Registration timing: **prospective**

Last update: **2019-12-12, 1398/09/21**

Update count: **0**

##### Registration date

2019-12-12, 1398/09/21

##### Registrant information

###### Name

sheno ghaderi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 87 3362 7228

###### Email address

ghaderi.sheno@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-06-20, 1399/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of topical magnesium sulfate on cervical edema in women admitted to childbirth ward of Imam Khomeini Hospital of Divandareh in 2019.

##### Public title

The effect of topical magnesium sulfate on cervical

edema during labor

IR.MUK.REC.1398.185

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 18-35 years Primiparous Gestational age 37-42  
Cephalic presentation Singleton BMI 19.8-30 NST  
reactive Willingness to participate in the study A history  
of severe dysmenorrhea History of infertility Narcotic use  
during pregnancy Attend birth statistics classes

### Exclusion criteria:

There are indications for cesarean section Maternal  
withdrawal from continuing study

## Age

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

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Using closed envelopes containing the letters A and B  
will be placed in one of the intervention (A) or control (B)  
groups, this will continue until the sample volume is  
completed.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kurdistan University of Medical  
Sciences

##### Street address

Imam Khomeini Street

##### City

Divandarreh

##### Province

Kurdistan

##### Postal code

13446666147

#### Approval date

2019-11-12, 1398/08/21

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

Cervical edema

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Cervical edema

#### Timepoint

Vaginal examination every 2 hours

#### Method of measurement

Edema based on touch of fluid accumulation in the cervix  
(which changes the thickness and consistency of the  
cervix) will be considered by the researcher and  
improvement of cervical edema means swelling returns  
to normal.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Using 50% magnesium sulfate vial  
made by Shahid Ghazi Pharmaceutical Company, The  
50% magnesium sulfate 50 cc will be poured onto the  
cervix by the researcher through a 10 cc syringe. And if  
the cervical swelling does not improve after two hours,  
10 cc of magnesium sulfate will be poured again on the  
cervix.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In the control group, 10 cc normal saline  
will be topically applied to the cervix by the researcher  
through a 10 cc syringe. And if the cervical swelling does  
not improve after two hours, 10 cc of normal saline will  
be poured on the cervix again.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Imam Khomeini Hospital  
**Full name of responsible person**  
Sheno Ghaderi  
**Street address**  
Imam Khomeini Street  
**City**  
Divandarreh  
**Province**  
Kurdistan  
**Postal code**  
6648456485  
**Phone**  
+98 87 3872 2930  
**Email**  
Ghaderi.sheno1366sg@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Sanandaj University of Medical Sciences  
**Full name of responsible person**  
Sheno Ghaderi  
**Street address**  
Imam Khomeini Street  
**City**  
Sanandaj  
**Province**  
Kurdistan  
**Postal code**  
13446666147  
**Phone**  
+98 87 3323 1458  
**Email**  
Ghaderi.sheno1366sg@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Kurdistan 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**  
Sanandaj University of Medical Sciences  
**Full name of responsible person**

Sheno ghaderi  
**Position**  
Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Imam Khomeini Street  
**City**  
Divandareh  
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**Postal code**  
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Ghaderi.sheno1366sg@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Sanandaj University of Medical Sciences  
**Full name of responsible person**  
Sheno Ghaderi  
**Position**  
Student  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Sanandaj University of Medical Sciences  
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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available