

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

Registration timing: **prospective**

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.

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

Update count: **0**

Registration date

2019-12-12, 1398/09/21

Design

Randomized clinical trial

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

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

Recruitment status

Recruitment complete

Funding source

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

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

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.

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.

Main outcome variables

Improve cervical edema

Public title

The effect of topical magnesium sulfate on cervical

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171210037807N2**

Registration date: **2019-12-12, 1398/09/21**

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
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Divandarreh
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6648456485
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Sponsors / Funding sources

1

Sponsor

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

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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