Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Randomized comparison of intravenous magnesium sulfate VS subligual nitroglycerin spray on Uterine hypercontractility during labor in Mahdieh-hospital

Protocol summary

Study aim

Effect of Intravenous Magnesium Sulfate and Sublingual Nitroglycerin Spray on Increased Uterine Activity in Labor in Pregnant Women Referred to Mahdie Hospital

Design

Pregnant women who undergo more than 5 contraction per minute for 10 minutes after the second phase of delivery after misoprostol or oxytocin or follow-up spontaneous pain after initial resuscitation measures one group of candidates receiving magnesium sulfate for 4 grams intravenous infusion within ten minutes and the other group receiving sublingual nitroglycerin spray puffs were repeated. After ten minutes the therapeutic response is evaluated and compared in terms of the number of contractions and the fetal heart rate. Standard treatment will be given to patients if they do not correct the fetal heart rate drop following these two medications

Settings and conduct

The study was performed at Mahdieh Hospital in Tehran.Patients entered the screening stage after receiving the necessary information about the trial and drug side effects, and if they wished to enter the study. Pregnant women who experienced more than five contractions in ten minutes after using misoprostol or oxytocin or following spontaneous pain before the second stage of labor.The study was conducted randomly and the participants entered the study only according to the necessary conditions in the entry criteria section

Participants/Inclusion and exclusion criteria

Entry requirements:Mothers who have had increased uterine contractility during labor. No entry conditions: Use any other medication to reduce contractions such as pethidine

Intervention groups

Intervention group 1: Magnesium sulfate 4 g intravenous infusion within ten minutes Intervention group II: receive a sublingual nitroglycerin spray puff

Main outcome variables

Magnesium Sulfate; Age of Pregnancy; Nitroglycerin Spray ; Extra Uterine Contractions ; Heart Rate Deficit; Emergency Cesarean

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045347N1**
Registration date: **2020-06-30, 1399/04/10**
Registration timing: **retrospective**

Last update: **2020-06-30, 1399/04/10**
Update count: **0**

Registration date

2020-06-30, 1399/04/10

Registrant information

Name

Maryam Azad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0980

Email address

azad@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Randomized comparison of intravenous magnesium sulfate VS subligual nitroglycerin spray on Uterine hypercontractility during labor in Mahdieh-hospital

Public title
Randomized comparison of intravenous magnesium sulfate VS subligual nitroglycerin spray on Uterine hypercontractility during labor in Mahdieh-hospital
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy women without underlying disease Single pregnancy pregnancy A healthy fetus with a normal heart rate Pregnancy over 37 weeks (semester and post semester) Spontaneous labor pain or induced by misoprostol or oxytocin
Exclusion criteria:
Contraindications to MgSo4 include Myasthenia Gravis, advanced muscle weakness, a history of allergy to MgSo4, severe renal impairment, and heart block. Restricted fetal growth, abnormalities and known fetal anomalies Fetal distress Chorioamnionitis placenta previa,placenta acaeta-increta-precreta Multiple pregnancies Patient dissatisfaction Polyhydramnios Previous cesarean section Oct positive test Take any medication other than multivitamins, multivitamins and iron Pregnant women with underlying diseases such as diabetes, high blood pressure, heart disease and so on Nitroglycerin contraindications Acute circulatory failure such as shock collapse system circulatory system Clear hypotension in systolic blood pressure less than 90 Severe anemia (hemoglobin less than 7)
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly assigned (Using random table of numbers) to be divided into two groups. One group of candidates received magnesium sulfate at 4 g intravenous infusion within ten minutes, and the other candidate received a subcutaneous spray of nitroglycerin spray. The even numbers will belong to the first group and the odd numbers will belong to the second group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2019-06-24, 1398/04/03
Ethics committee reference number
IR.SBMU.MSP.REC.1398.300

Health conditions studied

1

Description of health condition studied
increased uterine activity during childbirth
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
uterine activity during delivery
Timepoint
During delivery
Method of measurement
In the second stage of labor, the number of contractions will be recorded in ten minutes

Secondary outcomes

1

Description
number of uterine contractions
Timepoint

During excessive uterine activity during induction of labor

Method of measurement

More than 5 contraction within 10 minutes during induction of labor

Intervention groups

1

Description

Intervention group 1: Receiving magnesium sulfate in the amount of 4 g intravenous infusion within ten minutes.

Category

Treatment - Drugs

2

Description

Intervention group 2: Get a sublingual spray nitroglycerin spray puff.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

Maryam Azad

Street address

Shoush Square, Fadaiyan Eslam St , Glass House Alley , Shahid Rajab Nia St

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1185817311

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mahdiyeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak,

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tayebeh.jahed@yahoo.com

Grant name

.

Grant code / Reference number

.

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

No

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Azad

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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No. 8, Unit 6, West Golestan St., 22 Eskandar St., East Prophet, Ashrafi Isfahani Intersection

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Person responsible for scientific inquiries

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Full name of responsible person

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Position
MD
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Position
MD
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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