Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparision of maintenance therapy and continuous intravenous therapy with magnesium sulfate in preterm labor pain management at 24-36 weeks gestation: a randomized controlled trial

Protocol summary

Summary

The main objectivein of this single blind randomized clinical trial is comparision of maintenance therapy and continuous intravenous therapy with magnesium sulfate in preterm labor pain management.The study population are all of the patients with gestational age of 26 to 34 weeks. patients with at least 4 uterus contraction during 20 min and cervical dilatation below 4 cm and effacement less than 80% will enter in the study.The study sample size was 70 patients. Informed consent will be obtained from the participants they and will be randomly assigned to received with 4gr MS in 200cc D/W 5% during 15 to 20 minutes either infusion therapy with 20 gr MS in 10 hours (group A) or maintenance therapy with 2gr/hr MS for 12 hours (group B).Patients who will not response to magnesium sulfate within 2 h , will be excluded.We will assess the success rate in both groups for stopping labor pain, NICU admission, pregnancy duration and APGAR score at 5 min.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112913932N2**
Registration date: **2013-12-14, 1392/09/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-12-14, 1392/09/23

Registrant information

Name

Seyed Shojaeddin Namazi

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 1333 4190

Email address

ssh.namazi@gmail.com

Recruitment status

Recruitment complete

Funding source

Research council of Hormozgan University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of maintenance therapy and continuous intravenous therapy with magnesium sulfate in preterm labor pain management at 24-36 weeks gestation: a randomized controlled trial

Public title

the efficace of magnesium sulfate in preterm labor pain managment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:gestational age of 24 - 36 weeks;the presence of atleast 4 uterus contraction during 20 min; dilatation below 4 cm; effacement less than 80%

Exclusion criteria:coexistense of medical disease such as diabetes mellitus; asthma; cardiovascular disease; preeclampsia; uterine bleeding; rupture of membrane; placenta decolman; intruterine infections; UTI; fetus anomalies; previous preterm labor pain; lack of decreasing uterus contractions during 2 first hr after administration of magnesium sulfate; The patient need to administration of magnesium sulfate after 24 h.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
student research committee, Hormozgan University of Medical Sciences

Street address
Student Research Committee, Research Council, Shahid Mohammadi Hospital, Jomhoori Eslami Blvd Bandar Abbas Hormozgan Iran, Islamic Republic Of

City
Bandar Abbas

Postal code

Approval date
2013-09-23, 1392/07/01

Ethics committee reference number
88-92/29

Health conditions studied

1

Description of health condition studied
preterm labour pain

ICD-10 code
O60.1

ICD-10 code description
Preterm spontaneous labour with preterm delivery

Primary outcomes

1

Description
controlling uterine contraction

Timepoint
during intervention- 24 h after intervention

Method of measurement
checking uterine contraction by hand

2

Description
preterm delivery

Timepoint
just after intervention- 48 h after intervention

Method of measurement
, delivery before 37 weeks of gestation

Secondary outcomes

1

Description
duration of pregnancy

Timepoint
during and after intervention

Method of measurement
day

2

Description
Duration of neonatal admission in NICU

Timepoint
after intervention

Method of measurement
day

Intervention groups

1

Description
The patients in group A, will be received 4gr magnesium sulfate in 200cc D/W 5% during 15 to 20 minutes and then infusion of 20 gr magnesium sulfate during 10 hours (2gr/h)

Category
Treatment - Drugs

2

Description
The patients in group B, will be received 4gr magnesium sulfate in 200cc D/W 5% during 15 to 20 minutes and then continues infusion of 2gr/hr magnesium sulfate for

12 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fertility and infertility research center

Full name of responsible person

Seyed Shojaeddin Namazi

Street address

Fertility and infertility research center build. Shariati Hospital, Madar blvd. Bandar Abbas, Hormozgan.

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Abdolazim Nejatizadeh (Vice Chancellor of research Hormozgan University of Medical Sciences)

Street address

Research Council build., Shahid Mohammadi Hospital, Jomhoori Eslami Blvd

City

Bandar Abbas

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hormozgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Seyed Shojaeddin Namazi

Position

Student

Other areas of specialty/work

Street address

Student Research Committee, Research Counci Build., Shahid Mohammadi Hospital, Jomhoori Eslami Blvd.

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Person responsible for updating data

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Name of organization / entity

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty