Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Mg sulfate and Nifedipine effect on umbilical cord blood PH in neonates 23-36 age of gestation

Protocol summary

Summary

Main outcome : comparison of Mg-sulfate and Nifedipine effect on umbilical cord blood PH in 23-36 weeks neonates Design : Clinical trial , phase 2 or 3 clinical trial ,single centric Participants including major eligibility criteria : All of the pregnant women 23-36 weeks age of gestation with stable vital sign , intact amniotic membrane, no fetal abnormality were entered to the study and multi gestation and rupture of membrane were exported from the study. Sample volume : 60 pregnant women that divided to 2 groups .each group include 30 patients. Interventions : One group was treated with Mg-sulfate and another one was treated with Nifedipine. Time of interventions : 3o minutes after hydration and analgesic therapy. Main outcome : umbilical cord blood PH

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103025955N1**
Registration date: **2012-04-30, 1391/02/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-30, 1391/02/11

Registrant information

Name

Faezeh Moshayedi

Name of organization / entity

Hamedan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 81 1825 3333

Email address

f.moshayedi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University Of Medical Sciences

Expected recruitment start date

2011-03-23, 1390/01/03

Expected recruitment end date

2012-02-19, 1390/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Mg sulfate and Nifedipine effect on umbilical cord blood PH in neonates 23-36 age of gestation

Public title

the effect of Mg sulfate and Nifedipine effect on umbilical cord blood PH

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Pregnant women 23-36 week of gestation; intact amniotic membrane; No fetal abnormality in ultrasound; Single; Stable maternal vital sign. Exclusion Criteria: Rubture of membrane; multi gestation

Age

No age limit

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
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
Ethics and research committee of Hamedan University Of Medical Sciences
Street address
University Of Medical Sciences , Fahmideh Avenue , Hamedan
City
Hamedan
Postal code
65178/518
Approval date
2011-03-14, 1389/12/23
Ethics committee reference number
16/35/9/19/د/پ

Health conditions studied

1

Description of health condition studied
Cord PH in preterm neonates
ICD-10 code
068.3
ICD-10 code description
Labour and delivery complicated by biochemical evidence of fetal stress

Primary outcomes

1

Description
Umbilical Cord blood Ph In preterm Neonates
Timepoint
After Delivery
Method of measurement
Ph measure with Technomedia Blood Gass Device

Secondary outcomes

empty

Intervention groups

1

Description
In the second group, 30 minutes after hydration and analgesic agents , Nifedipine was initiated in this protocol : At first ,10 mg , and every 8 hours until 24 hours ; and then 20 mg every 8 hours , until the second 24 hours . And treatment was cut.
Category
Prevention

2

Description
In the first group, that accidentally were treated with Mg-sulfate, 30 minutes after hydration and analgesic agents , Mg sulfate was started in this protocol : 4 gr IV slow infusion in 10 minutes, after that 2 gr in 100 cc ringer lactete serum was continued until the uterine contractions were cut.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamedan Fatemieh Hospital
Full name of responsible person
Faezeh Moshayedi
Street address
Fatemieh Hospital , Kermanshah Street , Hamedan
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chncellor For Research Hamedan University Of Medical Siences
Full name of responsible person
Dr. Heidar Tavilani
Street address
Vice Chancellor For Research Hamedan University Of Medical Sciences, Fahmideh Avenue , Hamedan
City
Hamedan
Grant name

123900

Grant code / Reference number

123900-1

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

Yes

Title of funding source

Vice Chncellor For Research Hamedan University Of Medical Siences

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

Name of organization / entity

Hamedan University Of Medical Sciences

Full name of responsible person

Faezeh Moshayedi

Position

Resident Of Gynecology

Other areas of specialty/work

Street address

Fatemieh Hospital; Kermanshah Street ; Hamedan

City

Hamedan

Postal code

65177-89971

Phone

+98 81 1827 7012

Fax

+98 82 83939

Email

Dr_alimohamadi@yahoo.com ; f.moshayedi@umsha.ac.ir

Web page address

www.umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University Of Medical Siences

Full name of responsible person

Dr .Shohreh Alimohamadi

Position

Member of Gynecology Department Of Hamedan University of Medical Sciences

Other areas of specialty/work

Street address

Fatemieh Hospital ; Kermanshah Street ; Hamedan

City

Hamedan

Postal code

65177-89971

Phone

+98 81 1827 0713

Fax

+98 82 83939

Email

Dr-alimohamadi@yahoo.com

Web page address

www.umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University Of Medical Sciences

Full name of responsible person

Faezeh Moshayedi

Position

Resident Of Gynecology

Other areas of specialty/work

Street address

Fatemieh Hospital ; Kermanshah Street ; Hamedan

City

Hamedan

Postal code

65177-89971

Phone

+98 81 1827 7012

Fax

+98 82 83939

Email

f.moshayedi@umsha.ac.ir ; f_moshayedi@yahoo.com

Web page address

www.umsha.ac.ir

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