

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 : 30 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: Rupture 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 lactate 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 Tavailani

##### 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**  
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Resident Of Gynecology  
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## Person responsible for scientific inquiries

### Contact

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Dr .Shohreh Alimohamadi  
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Member of Gynecology Department Of Hamedan

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## Person responsible for updating data

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**Other areas of specialty/work**  
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## 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*