Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between the effect of magnesium sulfate alone and magnesium sulfate with celecxib to prevent spontaneous preterm labor in pregnant women

Protocol summary

Summary

In this randomized double-blind clinical trial, 164 singleton pregnant women with intact amniotic membranes, between 24-34 weeks gestational age, are enrolled with a diagnosis of preterm labor. they are assigned in two groups by colored cards. Magnesium sulfate is prescribed the first group at a dose of 4 grams and followed by two grams per hour intravenously for 24 hours, at the same time a 100-miligrams celecxib capsule is administered orally. In the second group magnesium sulfate with the same dose is given and placebo is prescribed instead of celecxib. Patients and the doctor who controls them are not aware of the kind of the consumed drug. Uterine contractions in both groups are recorded by tocometer every one hour. The first time that the uterine contraction decreases is considered as onset of drug action. If the uterine contractions do not remove after 8 hours, administering of celecxib or placebo continues every 8 hours for 24 hours. And if this way also do not prevent the uterine contraction after 24 hours, the case is recorded as treatment failure and treatment is stopped.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015042621947N1**
Registration date: **2016-05-18, 1395/02/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-18, 1395/02/29

Registrant information

Name

Shahin Nemati

Name of organization / entity

Kosar Hospital

Country

Iran (Islamic Republic of)

Phone

+98 28 3223 6374

Email address

sh.nemati@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Science

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of magnesium sulfate alone and magnesium sulfate with celecxib to prevent spontaneous preterm labor in pregnant women

Public title

Effect of Celecxib in order to prevent spontaneous preterm labor

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Singleton pregnancy; Intact amniotic

membrane; Gestational age between 24-34 weeks; Positive tocometry. Exclusion criteria: PROM; Vaginal bleeding; Chorioamnionitis; Dilatation more than 2 cm and cervical effacement exceeding 80%; Polyhydramnios; Oligohydramnios; Intrauterine Fetal Demise; Intrauterine Growth Restriction; Fetal distress; Smoking and alcohol abuse; systemic disease; Congenital anomalies; uterine anomalies; Celecxib intolerance.

Age
From **18 years** old to **46 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **164**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
82 yellow cards and 82 green cards have put in the box, for each patient with study including criteria, have exit one card randomly: green card for first group (magnesium sulfate alone) and yellow card for second group (magnesium sulfate with celecxib).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences

Street address
Bahonar Blvd, Qazvin, Iran

City
Qazvin

Postal code
4321102589

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
28/20/8859

Health conditions studied

1

Description of health condition studied
Preterm Labor

ICD-10 code
O60.1

ICD-10 code description
Preterm spontaneous labour with preterm delivery

Primary outcomes

1

Description
Preterm Labor

Timepoint
One hour after the onset of drug use until 24 hours

Method of measurement
Tocometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: initial dose 4 g of magnesium sulfate intravenously and then continuation of magnesium sulfate administration at a dose of 2g per hour for 24 hours with a 100 mg celecxib capsule and if needed its continuation every 8 hours for 24 hours

Category
Prevention

2

Description
Control group: initial dose 4g of magnesium sulfate intravenously and then continuation of magnesium sulfate administration at a dose of 2g per hour for 24 hours with a placebo capsule and if needed its continuation every 8 hours for 24 hours

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kosar Hospital

Full name of responsible person
Shahin Nemati

Street address
Kosar Hospital, Taleghani St, Qazvin, Iran

City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research of Qazvin University of Medical Sciences
Full name of responsible person
Shahin Nemati
Street address
Bahonar Blvd, Qazvin, Iran
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor for Research of Qazvin 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
Name of organization / entity
Qazvin University of Medical Sciences
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Farideh Movahed
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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