Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of delaying in premature labour by indomethacin and Mg sulfate in pregnant women referred to maternity hospital

Protocol summary

Summary

The aim of present study was to compare indometacin and Mg sulfate in delaying of premature labour pain. A randomized controlled trial was carried out on 60 pregnant women who were in 24-32 gestational age and referred to Shabihekhani hospital with painful uterine contraction and pressure in pelvic. The participants were randomly assigned into 2 equal groups. The control group received magnesium sulfate %20, 4 grams IV and 2gr/hour until stopping or decreasing of uterine contraction and if uterine contraction did not decreased after 1 hour, they would treat with 3gr magnesium sulfate. The intervention group received 50mg rectal suppository of indometacin and then continued every 6 hours until 24 hours. They would receive antibiotic if labor pain developed or uterine contraction didn't decrease or stop. Vital sign, vaginal bleeding, rupture membrane, duration of postponing of delivery, FHR, and uterine contraction were compared in 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811223329N1**
Registration date: **2010-09-30, 1389/07/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-09-30, 1389/07/08

Registrant information

Name

Zahra Sooki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

sooki_za@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Department of Kashan University of Medical Sciences

Expected recruitment start date

2008-08-22, 1387/06/01

Expected recruitment end date

2009-08-23, 1388/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of delaying in premature labour by indomethacin and Mg sulfate in pregnant women referred to maternity hospital

Public title

Comparison of delaying in premature labour by indomethacin and Mg sulfate in pregnant women referred to maternity hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: gestational age 24-32 based on LMP and sonography during first trimester, single pregnancy, intact membrane, lack of GI or kidney disease, myasthenia gravis Exclusion criteria: rupture membrane, vaginal bleeding, dilatation ≥ 5 centimeter, placenta and fetal abnormalities, allergy to indomethacin, tocolytic therapy

Age
From **15 years** old to **45 years** old
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
Kashan University of Medical Sciences and Health Services
Street address
Kashan University of Medical Sciences and Health Services, Ravand street
City
Kashan
Postal code
81151-89159
Approval date
empty
Ethics committee reference number
799/1/5/29/پ

Health conditions studied

1

Description of health condition studied
premature labour pain
ICD-10 code
060.0
ICD-10 code description
Preterm labour without delivery

Primary outcomes

1

Description
uterine contraction
Timepoint
every 15 minutes until 1 hour
Method of measurement
palpation of uterine contraction via abdomen

Secondary outcomes

1

Description
vaginal bleeding
Timepoint
during 48 hours
Method of measurement
self reporting

2

Description
rupture of membrane
Timepoint
during 48 hours
Method of measurement
self reporting

3

Description
duration of delivery delaying
Timepoint
during 48 hours
Method of measurement
control of contraction

4

Description
fetal heart rate
Timepoint
during 48 hours
Method of measurement
sonicade

Intervention groups

1

Description
Mg sulfate 4 gr %20, IV, during 20 minutes and then 2 gr until decreasing or stop of uterine contraction in IV infusion. If there was no decreasing in uterine contraction with 2 gr then 3 gr Mg sulfate was used.
Category
Treatment - Drugs

2

Description
Indomethacin, 50 mg, rectally, and then 50 mg every 6

hours until 24 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shabihekhani Maternity hospital

Full name of responsible person

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Dr hamidi

Street address

Kashan University of Medical Sciences and Health Services, Ravand road, Kashan

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan University of Medical Sciences and Health Services

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

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Zahra Sooky

Position

MS of midwifery/ Member of Faculty

Other areas of specialty/work

Street address

Kashan University of Medical Sciences and Health Services, Ravand street,

City

Kashan

Postal code

87159-81151

Phone

+98 36 1557 9191

Fax

Email

soki_z@kaums

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Elahe Mesdaghinia

Position

Gynecologist

Other areas of specialty/work

Street address

Kashan University of Medical Sciences and Health Services, Ravand street

City

Kashan

Postal code

87159-81151

Phone

+98 36 1557 9191

Fax

Email

mesdaghynia.elahe@ysahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Zahra Sooky

Position

MS of midwifery

Other areas of specialty/work

Street address

Kashan University of Medical Sciences and Health Services, Ravand street,

City

Kashan

Postal code

87159-81151

Phone

+98 36 1557 9191

Fax

+98 36 1555 6633

Email
soki_z@kaums.ac.ir
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