

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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)

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Email address

sooki_z@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 \geq 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

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Elahe Mesdaghinia

Position

Gynecologist

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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