Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of efficacy of indomethacin and magnesium sulphate in prevention of preterm labour on 28-32 weeks pregnant women referred to Alzahra maternity hospital in Tabriz

Protocol summary

Summary

The aim of this study was to compare the effects of indomethacin and magnesium sulfate in delaying delivery and compare maternal and neonatal outcome associated with the effects of the two drugs. This study is a randomized clinical trial. The study will be carried out on 150 pregnant women with a gestational age of 32-28 with a diagnosis of preterm labor so that have at least two uterine contractions are 30 seconds in the 10 minutes and cervical dilatation of less than 6-5 cm With cervical effacement of 60% -50% Who are admitted Tabriz Alzahra hospital. The patient will be excluded if rupture of amniotic membrane, Oligohydramnious, Vaginal bleeding and dilatation more than 5 cm. Patients will be randomly assigned to two equal groups of 75 people Patients Group (A): treated with 50% of the Pasteur Institute of magnesium sulfate 4 g intravenously within 20 minutes and will continue 2 gr IV infusion until to reduce or stop uterine contractions. In group B wont be treated with indomethacin suppository made in Iran, first 50 mg and then 50 mg every 6 hours until 24 hours. This study is not blind. Time delay in delivery and maternal morbidity and neonatal complications in two groups will be discussed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062613777N1**
Registration date: **2013-10-23, 1392/08/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-10-23, 1392/08/01

Registrant information

Name
Shamsi Abbasalizadeh

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 1553 9161

Email address
abbasalizadehs@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tabriz University of Medical Sciences

Expected recruitment start date

2013-08-06, 1392/05/15

Expected recruitment end date

2015-02-04, 1393/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of efficacy of indomethacin and magnesium sulphate in prevention of preterm labour on 28-32 weeks pregnant women referred to Alzahra maternity hospital in Tabriz

Public title

comparison of efficacy of indomethacin and magnesium sulphate in prevention of preterm labour

Purpose

Treatment

Inclusion/Exclusion criteria
Including criteria: 1- Pregnant women with gestational age of 32-28 weeks 1. Patients who have at least two or more than two contractions lasting 30 seconds during 10 minutes 2. Progress of dilation less than 5-6 cm 3.Effacement of cervix under 50-60% and also be ripe Excluding criteria: 1.Preterm Rupture of amniotic membranes 2.Oligohydramnious 3.Vaginal bleeding 4.nonassuring pattern of fetal heart 5. Allergic responses to indomethacin 6.Renal failure or Gastrointestinal
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Golgasht avenue
City
Tabriz
Postal code
5138665793
Approval date
2013-03-11, 1391/12/21
Ethics committee reference number
12325/4/5

Health conditions studied

1

Description of health condition studied
preterm Labour
ICD-10 code
O60.0
ICD-10 code description
Onset (spontaneous) of labour before 37 completed weeks of gestation

Primary outcomes

1

Description
Preterm birth
Timepoint
After intervening to fix premature contractions.
Method of measurement
Visual pain scale

Secondary outcomes

1

Description
Neonatal morbidity
Timepoint
After intervening until discharge neonatal from the NICU
Method of measurement
Check list

Intervention groups

1

Description
Intervention 1: magnesium sulfate (50%) of 4 mg IV over 20 min, and then 2 mg intravenous infusion every hours until the reduction or cessation of uterine contractions continue.
Category
Treatment - Drugs

2

Description
Case 2: Initially, 50 mg indomethacin , and then 50 mg every 6 hours for 24 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Dr.Shamsi Abbasalizadeh
Street address
Alzahra hospital,South Artesh
City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Tabriz University of Medical Sciences

Full name of responsible person

Dr. Alireza Ostad Rahimi

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

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,Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Shamsi Abbasalizadeh

Position

Associate Professor

Other areas of specialty/work

Street address

Tabriz university of medical sciences, Golgasht street

City

Tabriz

Postal code

5138665793

Phone

+98 41 1553 9161

Fax

Email

abbasalizadehs@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Shamsi Abbasalizadeh

Position

Associate Professor

Other areas of specialty/work

Street address

Tabriz university of medical sciences, Golgasht street

City

Tabriz

Postal code

5138665793

Phone

+98 41 1553 9161

Fax

Email

abbasalizadehs@tbzmed.ac.ir; wrhrcenter@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Shamsi Abbasalizadeh

Position

Associate Professor

Other areas of specialty/work

Street address

Tabriz University of Medical Sciences, Golgasht avenue

City

Tabriz

Postal code

5138665793

Phone

+98 41 1553 9161

Fax

Email

abbasalizadehs@tbzmed.ac.ir; wrhrcenter@gmail.com

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