Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of misoprostol / estradiol compared with misoprostol in labor induction

Protocol summary

Summary

Objective: Investigation the success rate of Estradiol in combination with Misoprostol in labor induction Design: Noting to Estradiol leads to an increase in Prostaglandin production, and Prostaglandin has a important role in onset of labor, we decided to investigate the effect of Estradiol on induction of labor. Setting and conduct: This study is a prospective clinical trial, double blind and randomization, with control group. The study will be performed in the Hospitals of Mashhad University of Medical Sciences on pregnant women who gestational age is upper 36 weeks and cervix is undesirable , and has indication of the termination of pregnancy will be done. The randomization is done by using closed envelopes by placing the referee for treatment in the envelope. Inclusion criteria included: Gestational age over 36 weeks, singleton pregnancy with a vertex presentation, the absence of contraindications to vaginal delivery, there is no indication for emergency childbirth, no history of liver and kidney disease, no history of fetal distributors, no history of contraindications use Misoprostol (such as the mother's risk of blood coagulation disorders, asthma, glaucoma, etc.).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120920264N1**
Registration date: **2017-10-29, 1396/08/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-29, 1396/08/07

Registrant information

Name

Seyedeh Azam Pourhoseini

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 3847 1446

Email address

pourhoseinia@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of misoprostol / estradiol compared with misoprostol in labor induction

Public title

Comparison of the effect of letrozole /Estradiol and Misoprostol in labor induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age over 36 weeks; singleton pregnancy with a vertex presentation; the absence of contraindications to vaginal delivery
Exclusion criteria: Indication for emergency childbirth;

History of liver and kidney disease; History of fetal distributors; History of contraindications use misoprostol (such as the mother's risk of blood coagulation disorders, asthma, glaucoma, etc).

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Mashhad University of Medical sciences

Street address
daneshgah St, Ghoreish department Mashhad , Islamic Republic Of Iran

City
Mashhad

Postal code
13944-91388 :

Approval date
2015-03-17, 1393/12/26

Ethics committee reference number
922107

Health conditions studied

1

Description of health condition studied
labor

ICD-10 code
O96.0

ICD-10 code description
Death from direct obstetric cause

Primary outcomes

1

Description
cervical ripening

Timepoint
The Bishop score less than 4 until the Bishop score of above 7

Method of measurement
vaginal exam

Secondary outcomes

1

Description
Duration of delivery

Timepoint
Every 4 hours

Method of measurement
vaginal exam

Intervention groups

1

Description
Intervention group:In this group, 25 microgram of Misoprostol vaginal cervix to start preparing favorable with 50 Micrograms of Estradiol (two pills Vagifom witch each pill contains 25 micrograms of Estradiol) will be used.

Category
Treatment - Drugs

2

Description
Control group: In this group to begin to prepare a favorable cervix, vaginal 25 micrograms of Misoprostol will be used.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Omolalbanin Hospital

Full name of responsible person
seyedeh azam pourhoseini

Street address
Omolalbanin Hospital, Ayatolah Bahjat Street

City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mahyar Mirheidari
Street address
Mashhad University of Medical Sciences; International Offic Administration Center (Qoreishi Building) ; Daneshgah St., Mashhad. Mashhad
City
Mashhad
Grant name
Grant code / Reference number
922107
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mashhad 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
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Person responsible for updating data

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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