Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of intravenous syntocinon in the third stage of labor with rectal misoprostol abortions after the second trimester of pregnancy

Protocol summary

Summary

In this randomized clinical trial, pregnant women at the gestational age of 14-28 weeks, referred with a letter from the Legal Medicine Organization for termination, or with other conditions such as intra-uterine fetal death and confirmed premature rupture of membranes, are selected. After giving a complete description of the abortion methods/medicines and their possible complications, as well as the research methodology, the eager patients are included in the study. The subjects are then randomly divided into two groups, and all of them receive the same protocol including 200 µg vaginal misoprostol every six hours. In case of a cesarean section history, a reduced dosage of misoprostol is prescribed for 48 hours, and if there is no response to this dosage, other methods such as intra-uterine catheter or high dose of syntocinon, depending on cervix condition and its dilatation, are used. After the removal of fetus and recording the operation time, an intravenous syntocinon including 40 units syntocinon in one liter normal saline is infused to the patients in Group 1 in an hour. The other group receives 400ug rectal misoprostol. Then, a period of one hour is given for the delivery of placenta and the exact time of delivery is recorded. The patient is monitored every quarter in this one hour period, and her vital signs including blood pressure, heart rate, and bleeding rate, measured based on the consumed pads, are recorded. If the placenta is not delivered in an hour and/or in case of the mother's unstable vital signs and/or severe vaginal bleeding, the patient is subjected to the curettage and the uterine contents are extracted and sent for pathological examination. If the placenta is delivered in an hour, the patient is undergone ultrasound to detect the pregnancy remnants. In case of a positive ultrasound result, the patient is subjected to curettage and the extracted uterine contents are sent for pathological examination to reach a definitive diagnosis. The time of the fetus delivery and the time interval between fetus and placenta removal, as well as the mother's bleeding level, measured based on the decline in hemoglobin rate are recorded (before the abortion and 24 after the abortion).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020715795N2**
Registration date: **2015-03-15, 1393/12/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-03-15, 1393/12/24

Registrant information

Name
babak sabzivand
Name of organization / entity
ardabil medical university
Country
Iran (Islamic Republic of)
Phone
+98 88 13472
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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

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 of intravenous syntocinon in the third stage of labor with rectal misoprostol abortions after the second trimester of pregnancy

Public title
Comparison of intravenous syntocinon in the third stage of labor with rectal misoprostol abortions after the second trimester of pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria were: legal permission to go to the end of pregnancy; intrauterine fetal death; gestational age 14 to 18 weeks; premature rupture approved exclusion criteria of the study: allergy or intolerance known as misoprostol; high blood pressure 160/90; severe cardiovascular disease; the patient's general condition is very bad; history of previous uterine scar (except single layer lower uterine segment caesarean section with a transverse incision); severe anemia; coagulation; anticoagulation; active liver disease; uncontrolled seizure disorders; Addison's disease; steroid use
Age
No age limit
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
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
Ardabil University of Medical Sciences
Street address
Ardabil University of Medical Sciences, Ardabil
City
Ardabil
Postal code
Approval date
2014-07-27, 1393/05/05
Ethics committee reference number
arums.rec.93.47

Health conditions studied

1

Description of health condition studied
Intravenous syntocinon in the third stage of labor associated with rectal misoprostol abortions after the second trimester of pregnancy
ICD-10 code
Y55
ICD-10 code description
Oxytocic drugs

Primary outcomes

1

Description
The time of placental removal
Timepoint
After fetus delivery
Method of measurement
Time

Secondary outcomes

empty

Intervention groups

1

Description
Two hundred micrograms of misoprostol administered vaginally every 6 hours with 40 units of syntocinon intravenously
Category
Treatment - Drugs

2

Description
Two hundred micrograms of misoprostol administered vaginally every 6 hours with 400 mcg of misoprostol rectal
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ardabil's Alavi Hospital
Full name of responsible person
Street address
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Akbar Pirzadeh
Street address
School of Medicine, Ardabil University of Medical Sciences, Ardabil, Iran
City
Ardabil
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Nooshin Mobaraki
Position
Assistant Professor of Obstetrics and gynecology
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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*