Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of effect of intra venuos Tranexamic acid and Misoprostol on Post Partum Hemorrhage and side effects of hemorrhage.

Protocol summary

Summary

In this study, the effect of intravenous administration of Tranexamic Acid and Misoprostol on postpartum bleeding will be checked. Patients with more than 500 ml bleeding after vaginal delivery and more than 1000 ml after cesarean are enrolled. Women, who have delivered vaginally or by cesarean section with spinal anesthesia in Al Zahra Hospital, are entered into the study. Women who have severe medical or surgical illness and have allergy an TXA or severe preeclampsia are excluded. The sample size is 200, which 100 people will be in each group. The first group after usual treatments gets 5 tablets of rectal misoprostol (200 microgram), another group will receive 1 gr intravenous TXA . If bleeding do not be controlled, TXA will be repeated after 30 minutes. Blood volume has been considered as the primary outcome. In this study, a patient, a doctor of medicine which is given to each of the two groups, are not aware. The questionnaire will be completed by a person unaware. In this study, Rate of primary HB Is compared after 12 and 24 hours, the need for transfusion, stability of the patient's hemodynamic and finally, effect of intravenous TXA and misoprostol will be compared..

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122411862N1**
Registration date: **2013-04-28, 1392/02/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-04-28, 1392/02/08

Registrant information

Name

Farnaz Sahaf

Name of organization / entity

Women's Reproductive Health Research Center

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

sahaf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Women's Reproductive Health Research Center

Expected recruitment start date

2013-01-04, 1391/10/15

Expected recruitment end date

2013-11-06, 1392/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of intra venuos Tranexamic acid and Misoprostol on Post Partum Hemorrhage and side effects of hemorrhage.

Public title

Evaluation of effect of intra venuos Tranexamic acid and Misoprostol on Post Partum Hemorrhage and side effects of hemorrhage.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: bleeding more than 500 mL after vaginal delivery and cesarean more than 1000 mm; willingness to participate in the study Exclusion criteria:

an acute medical or surgical conditions, including heart disease, liver, kidney and blood disorders; having allergy TXA; those who have thromboembolic disorders, women with high risk of pregnancy complications such as severe preeclampsia

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

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
Tabriz University of Medical Sciences

Street address
Third Floor, Central Building of Number2, Golgasht Street

City
Tabriz

Postal code
5138665793

Approval date
2012-11-12, 1391/08/22

Ethics committee reference number
8050/4/5

Health conditions studied

1

Description of health condition studied
Bleeding post Partum

ICD-10 code
O72

ICD-10 code description
haemorrhage after delivery of fetus or infant

Primary outcomes

1

Description
Bleeding

Timepoint
First 24 hours after childbirth or surgery

Method of measurement
Physical Examination

Secondary outcomes

1

Description
the need for transfusion

Timepoint
12 to 24 hours after delivery

Method of measurement
Questionnaire

Intervention groups

1

Description
The first group after the usual treatments get 5 tablets of rectal misoprostol 200 microgram

Category
Treatment - Drugs

2

Description
The second group:TXA intravenously 1 gr, IV

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person
Farnaz Sahaf

Street address
Alzahra hospital, Artesh jonoobi avenue

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chanecllor for research Tabriz University of Medical Sciences

Full name of responsible person
Doctor Seyed Kazem Shakouri
Street address
Tabriz University of Medical Ssciences, Golgasht avenue
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chanecllor 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
Farnaz Sahaf
Position
Associte proffesor
Other areas of specialty/work
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
Postal code
5138665793
Phone
+98 41 1553 9161
Fax
Email
sahaf@tbzmed.ac.ir; roya-fish@yahoo.cu; wrhrcenter@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farnaz Sahaf
Position
Associte proffesor
Other areas of specialty/work
Street address
Tabriz University of Medical Ssciences, Golgasht avenue
City
Tariz
Postal code
5138665793
Phone
+98 41 1553 9161
Fax
+98 41 1554 1221
Email
Sahaf@tbzmed.ac.ir; roya-fish@yahoo.cu; 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.Farnaz Sahaf
Position
Associte proffesor
Other areas of specialty/work
Street address
Alzahra Hospital
City
Tabriz
Postal code
5138665793
Phone
+98 41 1553 9161
Fax
+98 41 1554 1221
Email
Sahaf@tbzmed.ac.ir; roya-fish@yahoo.co.uk; 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