

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of effect of intra venous 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)

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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 venous Tranexamic acid and Misoprostol on Post Partum Hemorrhage and side effects of hemorrhage.

Public title

Evaluation of effect of intra venous 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

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Tabriz University of Medical Sciences, Golgasht
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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

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wrrcenter@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