

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative study of tranexamic acid on the prevention and decrease of Postpartum Hemorrhage in high-risk women

#### Protocol summary

##### Study aim

study of tranexamic acid on the prevention and decrease of postpartum Hemorrhage in high-risk women

##### Design

Has a control group, with parallel groups, three-way blind, randomized, on 214 patients. To randomize the random allocation list generated by PASS software

##### Settings and conduct

This study, which is performed as a three-blind clinical trial, is performed on 214 pregnant mothers in the educational, research, and treatment center of Umm Al-Banin in Mashhad. In order to conceal drug allocation, neither the participant nor the evaluator nor the researcher assisting in collecting information and checking for bleeding and hematocrit depletion and changes in vital signs is aware of any grouping.

##### Participants/Inclusion and exclusion criteria

Pregnant mothers at 37-40 weeks, age between 20 to 40 years, willingness to participate in the study, lack of quality of exit, the presence of post partum in the past, macrosomia over 4 kg, hydro polyamines, thromboembolic events, varicose veins of the lower extremities. And accumulation more than 24 hours and labor speedy and a little more and chorioamnionitis and the rest of the placenta. Outcomes of the study: Multiple pregnancies, placental abnormalities, preeclampsia, physical disorders, kidney, brain, and features ...

##### Intervention groups

In the intervention group, one gram of tranexamic acid will be injected immediately after delivery, and in the control group, only the same volume of the normal saline tranexamic acid vial will be injected. Both groups will receive 10 routine oxytocin units immediately after delivery. And in case of bleeding, all the necessary treatments for postpartum hemorrhage will be performed in both groups.

##### Main outcome variables

The amount of bleeding in the first 2 hours and 12 and 24 hours after delivery and the amount of hemoglobin

drop in both groups, participants will be evaluated for side effects of the drug.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101130005280N44**

Registration date: **2021-12-14, 1400/09/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-14, 1400/09/23**

Update count: **0**

##### Registration date

2021-12-14, 1400/09/23

##### Registrant information

##### Name

Raheleh Nejati

##### Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3711 2540

##### Email address

nejatir2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-21, 1400/08/30

##### Expected recruitment end date

2023-05-20, 1402/02/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of tranexamic acid on the prevention and decrease of Postpartum Hemorrhage in high-risk women

**Public title**

Comparative study of tranexamic acid

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

For pregnant mothers between 37-40 weeks, age between 20 to 40 years Satisfaction to participate in the study History of postpartum hemorrhage in previous pregnancy Macrosomic more than 4 kg Polyhydramnios History of thromboembolic events Lower limb varicose veins aggregate more than 24 hours Very fast labor and high parity Chorioamnionitis and placental abruption

**Exclusion criteria:**

Multiple pregnancies Placental abnormalities Preeclampsia Liver disorders Kidney, brain and ...

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **214**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method is simple among pregnant women 37-40 weeks with age between 20 to 40 years, patient allocation sequence will be done using blocked methods. Using the site sealedenvelope.com, four blocks of random sequence will be generated. Then, the sequence of assignment of the subjects in the two groups was included in the envelope, and based on the number of envelopes, the subjects were assigned to the two groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The subjects and those evaluating the outcome will be unaware of the intervention and control groups. Pregnant women will be randomly treated with an intervention and control regimen and do not know which group they belong to. Evaluate a group of researchers who do not know the details of the research

**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 Science

**Street address**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

**City**

MASHHAD

**Province**

Razavi Khorasan

**Postal code**

123456

**Approval date**

2018-12-25, 1397/10/04

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1397.571

**Health conditions studied****1****Description of health condition studied**

Occurrence of postpartum hemorrhage

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The amount of bleeding

**Timepoint**

In the first 2 hours (each quarter) and 12 and 24 hours after delivery

**Method of measurement**

Measure the amount of blood lost

**2****Description**

the amount of hemoglobin drop in both groups

**Timepoint**

In the first 2 hours (each quarter) and 12 and 24 hours after delivery

**Method of measurement**

The amount of hemoglobin is checked before and after delivery

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: In the intervention group, one gram of tranexamic acid will be injected immediately after delivery. Bleeding rate in the first 2 hours, 12 and 24 hours after delivery (measurement of bleeding volume by weighing gases and blood shanks, where each whole blood gas is equal to 10 cc of blood and long gas is equal to 50 cc of blood and sub-patient shans Blood loss (based on hemoglobin and hematocrit measured 24 hours after delivery) will be assessed in two groups.

### Category

Treatment - Other

2

### Description

In the control group, only the volume of tranexamic acid vial of normal saline will be injected. Bleeding rate in the first 2 hours, 12 and 24 hours after delivery (measurement of bleeding volume by weighing gases and blood shanks, where each whole blood gas is equal to 10 cc of blood and long gas is equal to 50 cc of blood and sub-patient shans Blood loss (based on hemoglobin and hematocrit measured 24 hours after delivery) will be assessed in two groups.

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Ghaem Hospital

#### Full name of responsible person

Hoda Hosseini

#### Street address

Ayatollah Behjat St. Umm Al-Banin Hospital

#### City

MASHHAD

#### Province

Razavi Khorasan

#### Postal code

99199-91766

#### Phone

+98 51 3841 3492

#### Email

Hoseinih961@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Majid Ghayour

#### Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

345 -91357

#### Phone

+98 51 3841 2081

#### Email

Hoseinih961@mum.sac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Mashhad University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Hoda Hosseini

#### Position

Assistant to obstetrician

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Ayatollah Behjat St. Umm Al-Banin Hospital

#### City

Mashhad

#### Province

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#### Postal code

99199-91766

#### Phone

+98 51 3841 3492

#### Email

Hoseinih961@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Farideh Akhlaghi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Email**

Hoseinih961@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hoda Hosseini

**Position**

Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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**Email**

Hoseinih961@mums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available