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 ortum 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 Scinces, 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 gase 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 gase 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
Razavi Khorasan
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

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

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
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

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