Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of tranexamic acid on blood loss during and after cesarean in women who candidate for cesarean section delivery by clinical trial study

Protocol summary

Summary

The purpose of this study was evaluation the prophylactic effect of tranexamic acid in blood loss during and after cesarean section. Primiparas and multiparas females with singleton pregnancy during the gestational ages of 37 to 40 weeks who are going to be delivered by cesarean section through Pfannenstiel's incision and spinal anesthesia are enrolled to the study. Patients with problem of heart, liver, kidney, hematologic or rheumatologic problems, history of thyroid disease, abnormal placental, severe preeclampsia, macrosomia, severe anemia and problematic obstetric history are not enrolled to the study. Patients who have allergy to Tranexamic acid are excluding from study. Patients are randomly placed in two groups equally. First group is receiving 1g intra venous tranexamic acid diluted with 20cc dextrose water 5% in operation room 15min before skin incision. Second group is receiving distilled water as placebo like this method. Total blood loss during the surgery and two hours later were measured through the amount of blood in suction machine and the weight of bloody pads, gauze and cloths. Variables include the effect of tranexamic acid on reducing blood loss during and after cesarean section, the need for blood transfusion, hysterectomy and evaluation of drug's side effects in mothers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405313485N4**
Registration date: **2014-09-09, 1393/06/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-09, 1393/06/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tranexamic acid on blood loss during and after cesarean in women who candidate for cesarean section delivery by clinical trial study

Public title

The effect of tranexamic acid on blood loss during and after cesarean in women who candidate for cesarean section delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Primiparas and multiparas females with singleton pregnancy during the gestational ages of 37 to 40 weeks who are going to be delivered by cesarean section through fannenstiel’s incision and spinal anesthesia Non-inclusion criteria: Patients with problem of heart, liver and kidney; hematologic or rheumatologic problems; history of thyroid disease; abnormal placental; severe preeclampsia; macrosomia; severe anemia; problematic obstetric history Exclusion criteria: allergy to Tranexamic acid

Age
From **135 years** old to **137 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice Chancellor for Research, Guilan University of Medical Sciences

Street address
Vice Chancellor for Research, Namjoo Street

City
Rasht

Postal code

Approval date
2014-08-19, 1393/05/28

Ethics committee reference number
1930231608

Health conditions studied

1

Description of health condition studied
Labour and delivery complicated by intrapartum haemorrhage, not elsewhere classified

ICD-10 code
0.72

ICD-10 code description
postpatrum-haemorrhage

Primary outcomes

1

Description
Blood loss during and two hours after surgery

Timepoint
During surgery until two hours

Method of measurement
Measuring the weight of bloody gauzes, pads and cloths during and two hours after the surgery and the amount of blood from the suction machine during the surgery

Secondary outcomes

1

Description
The need of blood transfusion

Timepoint
To 48 hours after a cesarean section

Method of measurement
Checking of hemoglobin and hematocrit during 12 to 24 hours after the surgery and checking vital signs every 4 hours

2

Description
The need of hysterectomy

Timepoint
To 48 hours after a cesarean section

Method of measurement
Checking vital signs and examination for Atonic uterus and abnormal vaginal bleeding every 4 hours

Intervention groups

1

Description
Giving 1g intra venous tranexamic acid diluted with 20cc dextrose water 5% in 15min before skin incision

Category
Treatment - Drugs

2

Description
Giving 1g intravenous distilled water as placebo diluted with 20cc dextrose water 5% in 15min before skin incision

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Dr. Roya Faraji
Street address
Alzahra hospital, Namjoo street
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Guilan University of Medical Sciences, Rasht, Iran
Full name of responsible person
Dr. Abtin Heidarzadeh
Street address
Vice Chancellor for Research, Guilan University of Medical Sciences, Namjoo street
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Guilan University of Medical Sciences, Rasht, Iran
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
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Full name of responsible person
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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