

Intravenous tranexamic acid use in elective caesarean section: Does it reduce blood loss?

Submission date 16/08/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/09/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/04/2010	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Intravenous tranexamic acid use in elective caesarean section: Does it reduce blood loss? A prospective randomised double-blind placebo controlled study

Study objectives
We know that, during delivery, when the placenta separates from the uterine wall, the fibrinolytic activation of the maternal blood increases and this tends to reduce the potential of blood to clot. This activation can last up to 6 - 10 hours postpartum, causing more bleeding.

According to this activation of the fibrinolytic system, we decided to use tranexamic acid (TA) to reduce the blood loss in the management of elective caesarean section (C/S) because TA inhibits this activation, thereby reducing bleeding.

As of 13/04/2010 this record was updated to include an amendment to the anticipated start date of this trial. The initial anticipated start date provided at the time of registration was 01/05/2009.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Istanbul Bakirkoy Women and Children Hospitals Local Ethics Board approved on the 18th March 2009 (ref: 185)

Study design

Prospective randomised double-blind placebo controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Elective caesarean section

Interventions

Following informed consent, simple randomisation using a random number table was performed by the investigational pharmacy staff. Infusion bags were prepared in accordance with randomisation and the bags labeled as A or B. One bag contained 1 g/10 mL tranexamic acid (Transamin, Fako Ilaclari A.S. Istanbul) diluted with 20 mL of 5 % glucose (Bag A, tranexamic group). The other bag contained only 20 mL of 5 % glucose (Bag B, placebo group).

Bag A was administered at least 10 minutes prior to skin incision (tranexamic acid 1 g/10 mL was given slowly intravenously over 5 minutes). After delivery of the neonate, 5 IU i.v. bolus of pre-prepared oxytocin was given by the anaesthetist. Then, 30 IU oxytocin in 500 mL of lactated Ringer's solution at a rate of 125 mL/h which was continued for 4 hours were given. An antibiotic, 1 g cefazolin diluted in 20 mL normal saline, was administered over a 5-minute period.

In the placebo group, 10 minutes before taking the skin incision 20 mL of 5% glucose was given slowly intravenously over 5 minutes. After delivery of the neonate, 5 IU i.v. bolus of pre-prepared oxytocin was given by the anaesthetist. Then, 30 IU oxytocin in 500 mL of lactated Ringer's solution at a rate of 125 mL/h which was continued for 4 hours were given. An antibiotic, 1 g cefazolin diluted in 20 mL normal saline, was administered over a 5-minute period. All caesarean sections were performed under general anaesthesia.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Tranexamic acid (TA)

Primary outcome(s)

Quantity of blood postpartum, measured from one day before the caesarean section and two days after the caesarean section

Key secondary outcome(s)

Measured from one day before the caesarean section and two days after the caesarean section:

1. Excessive bleeding rate
2. Blood transfusion
3. The use of additional uterotonic agents reflecting atony (such as an oxytocin infusion or Prostaglandin F2a)
4. Incidence of tranexamic acid side effects
5. Post-natal length of stay for the mother
6. Neonatal outcomes

Completion date

30/09/2009

Eligibility

Key inclusion criteria

1. Subjects older than 38 weeks estimated gestational age
2. Requiring elective caesarean section
3. Females aged 20 - 40 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Any risk factor associated with an increased risk of postpartum haemorrhage:

1. Anaemia (Hb less than 7 g%)
2. Multiple gestation
3. Antepartum haemorrhage
4. Uterine fibroids
5. Polyhydramnios
6. Emergency caesarean section
7. A history of uterine atony and postpartum bleeding

8. Current or previous history of significant disease including heart disease, liver, renal disorders or known coagulopathy

Date of first enrolment

01/06/2009

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

Türkiye

Study participating centre

Atakent Mah. Soyak Olypiakent Sitesi D10-57

Istanbul

Türkiye

34303

Sponsor information

Organisation

Istanbul Bakirkoy Women and Children Hospital (Turkey)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Istanbul Bakirkoy Women and Children Hospital (Turkey) - Department of Obstetrics and Gynecology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration