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

Submission date 16/08/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/09/2009	**Overall study status** Completed	
Last Edited 13/04/2010	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gokhan Yildirim

Contact details
Atakent Mah. Soyak Olypiakent Sitesi D10-57
K.Cekemece
Istanbul
Türkiye
34303
gokhan73yildirim@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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 transexamic 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 anaesthetis. 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)
Transexamic acid (TA)

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

Secondary outcome measures
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

Overall study start date
01/06/2009

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

Age group
Adult

Sex
Female

Target number of participants
660

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)

Sponsor details
Department of Obstetrics and Gynecology
Istanbul
Türkiye
34720

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration