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A study to measure the efficacy of tranexamic acid to reduce post partum haemorrhage volume

Submission date	Recruitment status	[_] Prospectively registered
19/02/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/05/2016	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PHRC 2004 1915

Study information

Scientific Title
A multi-centre open-label randomised controlled trial measuring the efficacy of tranexamic acid to reduce post partum haemorrhage volume

Acronym
EXADELI

Study objectives
A high dose tranexamic acid (TA) reduces a strictly measured ongoing Post-Partum Haemorrhage (PPH) volume.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the University Hospital of Lille, 04/01/2005

Study design
Multi-centre randomised controlled open-label 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
Post-partum haemorrhage

Interventions
Immediately after inclusion, patients were randomised to receive either TA (TA group) or no antifibrinolytic treatment (control group). The randomisation sequence was generated by a centralised computer and randomisation was balanced by centre. In the TA group, a dose of 4 grams of TA was mixed with 50 mL of normal saline and administered intravenously over an one-hour period. After the loading dose infusion, a maintenance infusion of 1g/hour was initiated and maintained for six hours.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tranexamic acid

Primary outcome measure
The volume of blood loss between enrollment and 6 hours later

Secondary outcome measures
1. Duration of bleeding and the impact of TA on PPH-related outcome [decrease in haemoglobin concentration, transfusion of packed red blood cells (PRBC) at T4 and at day 42, and the need for invasive procedures (uterine artery embolisation or ligature, hysterectomy), late post-partum curettage or general outcome (intensive care unit stay, use of any vasopressors, dyspnoea, renal and multiple organ failure)].
2. Severe PPH was defined according to Charbit et al. as exhibiting one of the following criteria:
2.1. Peri-partum decrease of haemoglobin > 4g/dL, with the last haemoglobin value before delivery considered as the reference
2.2. Transfusion of at least four packed red blood cells (PRBC)
2.3. Invasive haemostatic intervention
2.4. Death
Evaluation of each endpoint was performed by investigators blinded to treatment allocation.
3. Side effects: Although the study was not powered to address safety issues, side effects that could be related to TA were analysed. Major (thrombotic events, renal failure, seizures) and minor side effects were reported at each time point and at day 42. With respect to venous thrombosis, clinical signs of superficial or deep thrombosis were collected and ultrasonography was performed, as soon as the signs were detected.

Overall study start date
01/05/2005

Completion date
01/05/2008

Eligibility

Key inclusion criteria
Patients were included in the study when PPH was more than 800 mL

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
144

Key exclusion criteria
1. Age < 18 years
2. Asence of informed consent
3. Caesarean section
4. Presence of known haemostatic abnormalities before pregnancy
5. History of previous thrombosis or epilepsy

Date of first enrolment
01/05/2005

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
France

Study participating centre
Pole anesthesie reanimation
Lille
France
59037

Sponsor information

Organisation
University Hospital Research Delegation of Lille (France)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website

http://chru-lille.fr

ROR
https://ror.org/02ppyfa04

Funder(s)

Funder type
Government

Funder Name
French Ministry of Health (France)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2011		Yes	No
Results article	results	01/05/2016		Yes	No