

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

Submission date 19/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/05/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

The volume of blood loss between enrollment and 6 hours later

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Age < 18 years

2. Absence 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)

ROR

<https://ror.org/02ppyfa04>

Funder(s)

Funder type

Government

Funder Name

French Ministry of Health (France)

Results and Publications

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				

Results article		01/12/2011	Yes	No
Results article	results	01/05/2016	Yes	No