

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

<b>Submission date</b> 19/02/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/05/2016	<b>Condition category</b> 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

### Contact name

Dr Anne-Sophie Ducloy-Bouthors

### Contact details

Pole anesthesie reanimation  
maternite Jeanne de Flandre  
CHRU  
Lille  
France  
59037  
+33 (0)3 20 44 63 15  
asducloy@neuf.fr

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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. 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)

**Sponsor details**

2 Avenue Oscar Lambret

Lille

France

59037

+33 (0)3 20 44 59 62

valerie.santraine@chru-lille.fr

**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?
<a href="#">Results article</a>	results	01/12/2011		Yes	No
<a href="#">Results article</a>	results	01/05/2016		Yes	No