ISRCTN09968140 https://doi.org/10.1186/ISRCTN09968140

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

Registration date
24/03/2011

Overall study status
Completed

Last Edited
04/05/2016

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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

Primary study design
Interventional

Study design
Multi-centre randomised controlled open-label study

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. 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)

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