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St George's Hospital UK Study of the use of recombinant factor VIIa in pelvic fracture and acetabular reconstruction

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 10/07/2009	**Condition category** Surgery	

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

N0236106542

Study information

Scientific Title

Study objectives
This study will evaluate the possible effect of recombinant factor VIIa (rFVIIa) in the treatment of severe bleeding in severely injured trauma patients undergoing major orthopaedic reconstructive surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single centre randomised double-blind parallel group placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Acetabular reconstruction

Interventions
Use of recombinant factor VIIa in pelvic fracture and acetabular reconstruction

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Recombinant factor VIIa (rFVIIa)

Primary outcome measure
Total volume of perioperative blood loss

Secondary outcome measures
1. perioperative transfusion requirement (total volume of allogeneic blood components and salvaged RBC, total number of units of allogeneic blood components)
2. number of patients transfused with allogeneic blood components
3. total volume of crystalloid (Hartmann's solution, dextrose saline, normal saline) and colloid (succinylated gelatin) fluids infused
4. total operating time
5. time taken after entry to intensive care unit (ICU) or recovery unit to reach normal body temperature (36.337.1°C) and acidbase status (blood pH 7.357.45 with standard base excess 2 to +2)
6. time spent in ICU after surgery
7. days of hospitalization
8. number of times a patient was returned to the operating theatre

Overall study start date
01/06/2002

Completion date
31/03/2005

Eligibility

Key inclusion criteria
1. 1860 yr old
2. major pelvicacetabular fracture caused by trauma
3. scheduled for semi-elective large reconstruction surgery with the potential of blood loss exceeding 50% of circulating blood volume

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
1. history of thrombosis (deep vein thrombosis, pulmonary embolism, cerebral thrombosis)
2. severe head injuries or an abnormal CT scan of the head due to head injuries
3. base deficit of greater than 15 mEq litre1 or severe acidosis (pH<7.0.) before surgery

4. body weight exceeding 135 kg
5. known or suspected allergy to any drug that may be administered during the course of the study
6. cardiac arrest after trauma and before surgery at St George's Hospital
7. known congenital bleeding disorders
8. known pregnancy or positive pregnancy test at enrolment
9. previous participation in this study
10. previous receipt of rFVIIa within 48 h of screening
11. currently participating or having participated in another investigational drug study within the last 30 days

Date of first enrolment
01/06/2002

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Adult Intensive Care Unit
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St George's Healthcare NHS Trust (UK)

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	01/05/2005		Yes	No