

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2009	Condition category Surgery	<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

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 pelvicaacetabular 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

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