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Use of recombinant activated Factor Seven in bleeding extracorporeal membrane oxygenation patients post cardiac surgery: a randomised prospective study

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/05/2015	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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

N0012154243

Study information

Scientific Title
Use of recombinant activated Factor Seven in bleeding extracorporeal membrane oxygenation patients post cardiac surgery: a randomised prospective study

Study objectives
Will an early use of Factor Seven (FVII):
1. Stop bleeding?
2. Reduce use of other blood products?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised 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
Extracorporeal membrane oxygenation (ECMO) patients post cardiac surgery

Interventions
1. Use of FVII
2. Placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Amount of post-operative bleeding
2. Use of human blood products

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2004

Completion date
31/03/2006

Eligibility

Key inclusion criteria
Post cardiac surgery patients

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
40

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2004

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital
London

United Kingdom
WC1N 3JH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Great Ormond Street Hospital for Children NHS Trust / Institute of Child Health (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