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BAIL-OUT: 'Bail-out Anticoagulation in coronary Intervention TriaL - OUTcomes': a randomised comparison of the real world use of bivalirudin versus abciximab as a 'bail out' anticoagulant following heparin in percutaneous coronary intervention with focus on patient safety

Submission date 07/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/01/2007	**Overall study status** Completed	
Last Edited 10/07/2017	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-003343-23

Protocol serial number
UHL 10145

Study information

Scientific Title
BAIL-OUT: 'Bail-out Anticoagulation in coronary Intervention TriaL - OUTcomes': a randomised comparison of the real world use of bivalirudin versus abciximab as a 'bail out' anticoagulant following heparin in percutaneous coronary intervention with focus on patient safety

Acronym
BAIL-OUT

Study objectives
Non-inferiority exists in terms of bleeding complication rates between bivalirudin and abciximab (ReoPro) when used as provisional (Bail-out) anticoagulants during Percutaneous Coronary Intervention (PCI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire and Rutland REC 1, 13/10/2006, ref: 06/Q2501/197

Primary study design
Interventional

Study design
Single-centre open-label randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
Provisional bivalirudin versus provisional Abciximab following bolus heparin (65 u/kg) during PCI. The trial anticoagulant is given as per normal protocol, i.e., Bivalirudin bolus 0.75 mg/kg followed by infusion of 1.75 mg/kg/hr for duration of procedure only and Abciximab bolus and infusion for 12 hours.

Data collected from baseline, day of discharge post PCI and 30 days post PCI.

Intervention Type
Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)
Bivalirudin, abciximab (ReoPro), heparin

Primary outcome(s)
Major and minor bleeding complication rate

Key secondary outcome(s)
1. Major Adverse Coronary Events (MACE)
2. Peri-procedural Troponin T level

Completion date
01/04/2008

Eligibility

Key inclusion criteria
Patients undergoing planned elective PCI at Leicester Glenfield Hospital without requirement for up-front GlycoProtein (GP) IIb IIIa after consent from patient and operator, randomised when Bail out situation is deemed to have occurred by the operator, which requires additional anticoagulation. There will be no limitation of concomitant therapy. All therapeutic regimens will be documented on the Case Report Form (CRF).

Indications for additional anticoagulation (and hence randomisation) will include but not be restricted to:
1. Abrupt or side-branch closure
2. Obstructive dissection
3. New or suspected thrombus
4. Impaired or slow coronary blood flow
5. Distal embolisation of thrombus
6. Persistent residual stenosis
7. Unplanned stent placement
8. Prolonged ischaemia
9. Other clinical instability or at discretion of the operator

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria

1. Any contra-indication to Bivalirudin or ReoPro as per product licence
2. Primary PCI for acute myocardial infarction
3. Uncontrolled sustained Blood Pressure (BP) more than 200/110 mmHg
4. Previous PCI within one month
5. Active bleeding, surgery, trauma or Gastro-Intestinal (GI) bleeding within 6/52
6. Serious intracranial pathology or previous bleed
7. Disseminated malignancy
8. Potential bleeding diathesis or other contra-indication to anticoagulation
9. Platelet count less than 100
10. Serum creatinine more than 350 or dialysis dependent
11. Abciximab within seven days, eptifibitide or tirofiban within 12 hours
12. Any other medical condition, or the presence of extreme age or general frailty which would lead operator to reduce dose or omit anticoagulants in normal practice

Date of first enrolment
01/11/2006

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Glenfield Hospital
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
University Hospitals of Leicester NHS Trust (UK)

Funder Name
Nycomed UK Ltd (UK) will provide a small research grant (to cover consumables and admin costs); Nycomed have no rights to any future publications or input into design or conduct of the study

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration