

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/07/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anthony Gershlick

Contact details
Clinical Sciences Department
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP
+44 (0)116 256 3021
agershlick@aol.com

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

Study design

Single-centre open-label randomised controlled trial

Primary study design

Interventional

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, eptifibatid 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