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A Randomized Trial Comparing Same Day Discharge and a Single Bolus of Abciximab to Overnight Hospitalization and Bolus + Perfusion Abciximab After Uncomplicated Trans-Radial Coronary Artery Stenting

Submission date
05/01/2005

Registration date
04/02/2005

Last Edited
18/10/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Olivier Bertrand

Contact details
2725 Chemin Ste Foy
Quebec
Canada
G1V 4G5
+1 418 656 8711 ext 3136
olivier.bertrand@crhl.ulaval.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00169819

Secondary identifying numbers
H4S-CA-0050

Study information

Scientific Title

Acronym
EArly discharge after trans-radial Stenting of coronarY arteries: The EASY study

Study objectives
1. Discharge on the same day after uncomplicated trans-radial coronary artery stenting is safe and effective.
2. Hospitalized patients can be safely returned to the referring center the same day following trans-radial coronary artery stenting.
3. Abciximab given as a single bolus with optimal trans-radial coronary artery stenting is as safe and effective as bolus + 12 hrs perfusion and does not hamper early discharge.
4. Same-day discharge is cost-effective and increases patient satisfaction.

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
Single-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Angina

Interventions

Patients with stable or unstable angina referred for catheterization and possible percutaneous intervention are eligible.

After diagnostic trans-radial catheterization, patients receive a bolus of Abciximab and undergo dilatation and stent implantation. At the end of the uncomplicated procedure, patients are randomized between group 1: No perfusion of Abciximab and discharge 4-6 hours after PCI and group 2: Standard 12 hours Abciximab perfusion and overnight hospitalization. In case of complications, patients are included in a registry and receive standard 12 hours Abciximab perfusion. Electrocardiogram (ECG) and biology tests (creatine kinase [CK] CK-myocardial band [CK-MB], troponins) are performed before, 4-6 hours after and the next day after PCI. Clinical follow-up is performed at 24 hours, 30 days, 6 months and 1 year after PCI.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Abciximab

Primary outcome measure
The primary end-point of the study is the composite of death, myocardial infarction, repeat hospitalization, urgent revascularization, severe thrombocytopenia, access site complications and major bleedings at 30 days following stent implantation.

Secondary outcome measures
The secondary end-point is the composite of death, myocardial infarction, repeat target vessel revascularization at 30 days, 6 months and 1 year following stent implantation. Other secondary end-points include the total hospital stay (days) between the index procedure and the first 30 days follow-up, the number of unsolicited medical visits in relation with the percutaneous procedure, index of patient satisfaction and direct and indirect costs.

Overall study start date
15/10/2003

Completion date
29/04/2005

Eligibility

Key inclusion criteria
Approximately 1000 patients undergoing 'adhoc' percutaneous coronary intervention (PCI) will be randomized.

Inclusion Criteria:
1. Patients with documented ischemic coronary artery disease and scheduled for possible coronary artery stenting are eligible.
2. Patient must be >18 years of age.
3. Patient and treating interventional cardiologist agree for randomization.

4. Patient will be informed of the randomization process and will sign an informed consent.
5. Diagnostic and therapeutic intervention performed through trans-radial/ulnar artery approach.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
CLINICAL:
1. Patients with recent (<72 hrs) Q-wave (ST elevation) acute myocardial infarction
2. History of LV ejection fraction ≤30%
3. Unstable clinical condition
4. Any complication compromising ambulation
5. Concurrent participation in other investigational study requiring prolonged hospitalization
6. Required prolonged hospitalization
7. Incath lab transient vessel closure
8. Resuscitation per PCI
9. Hemodynamic collapse during PCI
10. Severe entry site complication upon investigator decision
11. Social isolation
12. Serious cognitive disorders
13. Femoral sheath (artery)
14. Persisting chest pain
15. No ASA prior PCI
16. Allergy to ASA or thienopyridines precluding treatment for 30 days
17. Any significant blood dyscrasia
18. PCI without stent implantation (except for bifurcation lesion or re-dilatation for in-stent restenosis)
19. International Normalised Ratio (INR) >2.0
20. Contraindication to Reopro administration

ANGIOGRAPHIC:
1. Residual dissection of grade ≥B of NHBLI classification
2. Compromised or sub-occluded branch with diameter ≥ 1 mm
3. Timi <3 post-stenting
4. Thrombus post-PCI

Date of first enrolment
15/10/2003

Date of final enrolment
29/04/2005

Locations

Countries of recruitment
Canada

Study participating centre
2725 Chemin Ste Foy
Quebec
Canada
G1V 4G5

Sponsor information

Organisation
Laval Hospital Research Center (Canada)

Sponsor details
2725 Chemin Ste Foy
Quebec
Canada
G1V 4G5
+1 418 656 8711
olivier.bertrand@crhl.ulaval.ca

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
This Study is an Investigator Initiated Trial, which is supported by unrestricted grants from Eli-Lilly and Bristol-Myers-Squibb (Canada)

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	12/12/2006		Yes	No