# 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	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>	
05/01/2005		Protocol	
Registration date	Overall study status	Statistical analysis plan	
04/02/2005	Completed	[X] Results	
<b>Last Edited</b> 18/10/2007	<b>Condition category</b> Circulatory System	Individual participant data	

**Plain English summary of protocol**Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

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### Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

#### 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  $\geq 1$  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

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#### 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