# Endeavor primary percutaneous coronary intervention (PCI) study

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
23/04/2010		Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
23/04/2010		[X] Results		
<b>Last Edited</b> 22/07/2013	Condition category Circulatory System	[] Individual participant data		

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr John Greenwood

#### Contact details

Academic Unit of Cardiovascular Medicine Great George Street Leeds United Kingdom LS1 3EX

# Additional identifiers

Protocol serial number 4963

# Study information

#### Scientific Title

Evaluation of the clinical performance of the Medtronic Endeavor ABT-578 eluting coronary stent system in patients undrgoing primary percutaneous coronary intervention (PCI) for acute myocardial infarction

## Study objectives

Primary percutaneous coronary intervention (PPCI) is superior to thrombolysis in patients with ST elevation acute myocardial infarction (STEMI). Furthermore, drug eluting stents (DES) have been shown to be superior to bare metal stents (BMS) for reduction in clinical restenosis rates. Data on late stent thrombosis (greater than 30 days) raise concerns about DES placement in a patient with an acute coronary syndrome. Recent studies using sirolimus and paclitaxel-eluting stents in the PPCI setting have been published and suggestequivalence or superior outcomes compared to BMS. We aim to evaluate the Medtronic Endeavor ABT-578 eluting coronary stent system in patients undergoing PPCI.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Leeds (West) Research Ethics Committee approved on the 7th September 2006 (ref: 06/Q1205/171)

## Study design

Non-randomised interventional treatment trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

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

Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

#### **Interventions**

Consecutive patients presenting with an STEMI within 12 hours of onset of symptoms when the clinical decision was to undergo Primary PCI, were invited to participate. All subjects received one or more Medtronic Endeavor ABT-578 eluting coronary stent in one or more target lesions. All subjects to be followed for 3 years.

#### Intervention Type

Drug

#### Phase

Not Applicable

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

**ABT-578** 

#### Primary outcome(s)

Major adverse cardiac event at 30 days post PPCI

## Key secondary outcome(s))

Major adverse cardiac event at 6, 12 and 36 months.

#### Completion date

01/05/2007

# Eligibility

#### Key inclusion criteria

- 1. The patient is greater than 18 years, either sex
- 2. The patient has consented to participate by signing the Patient Informed Consent Form and /or has authorised the collection and release of his medical information by signing the patient Data release Consent form
- 3. The patient has presented with 12 hours of onset symptoms, and the clinical decision has been made to undergo primary PCI
- 4. Patient was suitable for implantation of one or more of the Endeavor ABT-578 Eluting Coronary Stent System, in one or more native artery target lesions
- 5. Lesion length and vessel diameter of the target lesion(s) are according to the Indications for Use that comes with every Endeavor ABT -578 Eluting Coronary Stent System
- 6. The patient is willing and able to cooperate with the registry procedures and required telephone contacts

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

## Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Women with known pregnancy or who are lactating
- 2. Patients with hypersensitivity or allergies to aspirin, heparin, clopidogrel, ticlopidine, drugs such as ABT-578, rapamycin, tacroloimus, sirolimus or similar drugs or any analogue or dervative, cobalt, chromium, nickel, molybdenum or contrast media
- 3. Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated
- 4. Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon
- 5. Current medical condition with a life expectancy of less than 12 months
- 6. The subject is participating in another device or drug study. Subject must have completed the follow up phase of any previous study at least 30 days prior to enrolment in this trial. The subject may only be enrolled in this registry once.
- 7. Patients with medical conditions that preclude the follow up as defined in the protocol or that otherwise limits participation in this registry
- 8. Patients who are haemodynamically unstable (cardiogenic shock)
- 9. Patients who have a myocardial infarction in a non native coronary artery

#### Date of first enrolment

# Date of final enrolment 01/05/2007

# Locations

## Countries of recruitment

**United Kingdom** 

England

Study participating centre
Academic Unit of Cardiovascular Medicine
Leeds
United Kingdom
LS1 3EX

# Sponsor information

## Organisation

Medtronic Ltd (UK)

#### **ROR**

https://ror.org/00grd1h17

# Funder(s)

## Funder type

Industry

#### **Funder Name**

Medtronic PLC (UK)

# **Results and Publications**

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	01/12/2011		Yes	No