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Endeavor primary percutaneous coronary intervention (PCI) study

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Major adverse cardiac event at 30 days post PPCI

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

Overall study start date
21/08/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100

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
21/08/2006

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Medtronic Ltd (UK)

Sponsor details
Building 9
Crossley Green Business Park

Watford
United Kingdom
WD18 8WW

Sponsor type
Industry

Website
http://www.medtronic.co.uk/about-medtronic/medtronic-uk/index.htm

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Industry

Funder Name
Medtronic PLC (UK)

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	01/12/2011		Yes	No