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Optical Coherence Tomography Assessment of Gender diVersity In Primary Angioplasty. The OCTAVIA Trial

This study has been completed.

Sponsor:
Italian Society of Invasive Cardiology

Collaborator:
Meditrial SrL

Information provided by (Responsible Party):
Italian Society of Invasive Cardiology

ClinicalTrials.gov Identifier:
NCT01377207

First received: January 25, 2011
Last updated: April 18, 2013
Last verified: April 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Tracking Information	
First Received Date ICMJE	January 25, 2011
Last Updated Date	April 18, 2013
Start Date ICMJE	January 2011
Primary Completion Date	January 2013 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE **(submitted: June 20, 2011)**	• Percentage of ruptured or eroded plaques at infarct related lesion as assessed by OCT before PCI [Time Frame: Plaque rupture is evaluated during the index PCI procedure.] [Designated as safety issue: No] To assess gender differences in the percentage of ruptured or eroded plaques at infarct related lesion as assessed by OCT. The OCT measurement is taken before stenting, when a TIMI flow 2-3 is detected. If baseline flow is TIMI 1, thrombus aspiration is performed before OCT. • Percent of covered stent struts by OCT in infarct-related lesion at 9 months (co-primary endpoint). [Time Frame: Stent coverage is evaluated at 9 months by OCT performed in all patients.] [Designated as safety issue: Yes] To assess gender differences in the percentage of covered stent struts at infarct related lesion as assessed by OCT performed in all patients at 9 months.
Original Primary Outcome Measures ICMJE	*Same as current*
Change History	Complete list of historical versions of study NCT01377207 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE **(submitted: June 20, 2011)**	• Minimal Fibrous Cap Thickness (MFCA) (μm) at infarct-related lesion as determined by OCT. [Time Frame: MFCA at index procedure (immediately after reestablishment of TIMI 2-3 coronary flow by PCI) and at 9 months OCT performed in all patients.] [Designated as safety issue: No] To assess gender differences in Minimal Fibrous Cap Thickness at infart related lesion by OCT immediataly after reestablishment of TIMI (Thrombolysis In Myocardial Infarction) 2-3 coronary blood flow and before stent implantation. The evolution of fibrous cap thickness over time will be determined by OCT that will be performed in all patients at 9 months from the index procedure. • Presence and type of residual thrombus material in the culprit vessel. [Time Frame: Residual thrombus in the infarct related vessel is evaluated during the index procedure: immediately after reestablishment of TIMI 2-3 coronary flow during primary percutaneous coronary intervention] [Designated as safety issue: No] To assess gender differences in thrombus type by OCT in culprit vessel after reestablishment of TIMI (Thrombolysis In Myocardial Infarction) 2-3 coronary blood flow and before stent implantation. • Number of TCFA (<65 μM) as assessed by OCT in the culprit vessel (infarct related). [Time Frame: Thin Fibrous Cap Atheroma is assessed during the index procedure: immediately after reestablishment of TIMI 2-3 coronary flow before stent implantationduring PCI; and at 9 months by OCT performed in all patients.] [Designated as safety issue: No] To assess gender difference in TCFA number as assessed by OCT in the infarct related vessel during the

	index procedure and at 9 months by OCT performed in all patients • percent of malapposed-uncovered struts [Time Frame: 9 months] [Designated as safety issue: Yes] to assess gender difference in % malapposed/uncovered struts at 9 months follow up by OCT • percent net volume obstruction [Time Frame: 9 months] [Designated as safety issue: No] To assess gender difference in % of stent volume obstruction by OCT at 9 months follow up • percent abnormal intraluminal tissue [Time Frame: 9 months] [Designated as safety issue: Yes] To assess gender difference in % of abnormal intraluminal tissue by OCT at 9 months follow up
Original Secondary Outcome Measures ICMJE	*Same as current*
Current Other Outcome Measures ICMJE	*Not Provided*
Original Other Outcome Measures ICMJE	*Not Provided*

Descriptive Information

Brief Title ICMJE	Optical Coherence Tomography Assessment of Gender diVersity In Primary Angioplasty. The OCTAVIA Trial
Official Title ICMJE	Optical Coherence Tomography Assessment of Gender diVersity In Primary Angioplasty. The OCTAVIA Trial
Brief Summary	Recent studies suggest important gender differences in the pathophysiology and prognosis of ST-segment elevation myocardial infarction (STEMI). This is the first prospective controlled study to assess gender differences in the mechanism of plaque rupture/erosion and thrombus formation in patients presenting with STEMI treated with primary angioplasty. Gender-related mechanisms of plaque rupture or erosion will be investigated using a combination of Quantitative Coronary Angiography, high resolution Optical Coherence Tomography of the culprit vessel and histopathologic analyses of thrombus aspirates of the infarct related lesion, performed by independent core laboratories, blinded to group (male or female) and clinical variables.
Detailed Description	In OCTAVIA; enrollment in a 1:1 ratio according to gender group will be ensured by a computer-assisted matching algorithm for gender and age (< 50, 51-70, and > 70 years). Matching has the purpose to enable enrollment of an even number of male and female patients in balanced age groups. This type of dynamic algorithm is appropriate when the composition of the referral population is not known in advance. OCTAVIA will assess gender differences in the mechanism of plaque rupture. The study will also evaluate the changes in the vascular territory remote from the infarct related lesion, the local vascular response to primary angioplasty interventions and the correlation with clinical outcomes over one year of follow-up. These data are important to support a gender based differential strategy and can have a substantial impact for the improvement of clinical practice in the treatment of women with STEMI. The study sample of 140 patients is sized to address the hypothesis that the female population has a lower prevalence of plaque rupture (primary endpoint) at baseline OCT than the male population. Computations were conducted assuming a prevalence of rupture of 82% in males and 60% in female patients (22% lower). Confirmatory power calculation was performed on the basis of stent Strut Coverage at 9 month follow-up (co primary endpoint). Stent-strut coverage and apposition have been linked to the risk of stent thrombosis. However, our understanding of DES healing in male and female patients with ST-segment elevation myocardial infarction is restricted to post-mortem data. The investigators assumed a per patient stent strut coverage (a continuous variable with right skewed distribution) with mean of 97.0% and standard deviation of 4.0% in men, versus mean of 95.0% and standard deviation of 4.0% in women, following Xience Prime implantation. Thus, aiming for a 5% 2-tailed superiority alpha, an 80% power, and assuming a 1:1 enrollment according to gender, a total of 64 patients per group should be enrolled. Anticipating a 10% dropout rate due to patients lost to follow-up and inadequate imaging (included major side branch sections), the total enrollment is set at 70 patients per group (total population of 140 subjects).
Study Type ICMJE	Interventional
Study Phase	Phase 4
Study Design ICMJE	Allocation: Randomized Endpoint Classification: Safety/Efficacy Study Intervention Model: Parallel Assignment Masking: Single Blind (Outcomes Assessor) Primary Purpose: Treatment
Condition ICMJE	Acute Myocardial Infarction
Intervention ICMJE	Procedure: Primary PCI Thrombus aspiration and hystopathological analysis, Optical Coherence Tomography assessment of STEMI

	culprit vessel, Primary PCI with Drug Eluting Stent implantation; Repeat OCT assessment of culprit vessel at 9 monts follow-up
Study Arm (s)	• Experimental: Female Arm Female gender diagnosed with ST segment Elevation Myocardial Infarction (STEMI) Intervention: Procedure: Primary PCI • Active Comparator: Male Arm Male Gender diagnosed with ST segment Elevation Acute Myocardial Infarction (STEMI) Intervention: Procedure: Primary PCI
Publications *	*Not Provided*

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE	Completed
Enrollment ICMJE	140
Completion Date	April 2013
Primary Completion Date	January 2013 (final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	Inclusion Criteria: • Acute Myocardial MI with ST segment Elevation, within 6 hours from symptoms onset • Native coronary artery disease (no prior stent implant, no prior brachytherapy) • Signed patient informed consent Exclusion Criteria: • Patients with left main disease • infarct lesions in bypass grafts • cardiogenic shock • renal failure • recent major bleeding • allergy to aspirin or clopidogrel • on anticoagulant therapy • no suitable anatomy for OCT (extreme tortuousity, very distal culprit lesion, and large infarct vessel > 4 mm in diameter)
Gender	Both
Ages	18 Years and older
Accepts Healthy Volunteers	No
Contacts ICMJE	*Contact information is only displayed when the study is recruiting subjects*
Location Countries ICMJE	Italy

Administrative Information

NCT Number ICMJE	NCT01377207
Other Study ID Numbers ICMJE	27/01/2011
Has Data Monitoring Committee	Yes
Responsible Party	Italian Society of Invasive Cardiology
Study Sponsor ICMJE	Italian Society of Invasive Cardiology
Collaborators ICMJE	Meditrial SrL

Investigators ICMJE	Principal Investigator: Giulio Guagliumi, MD — Italian Society of Invasive Cardiology
Information Provided By	Italian Society of Invasive Cardiology
Verification Date	April 2013

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**