MGuard Prime Stent System Clinical Trial in Patients with Acute ST Elevation Myocardial Infarction*.

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The objective of this study is to evaluate the safety and efficacy of the MGuard* Prime stent in the treatment of de novo stenotic lesions in coronary arteries in patients undergoing primary PCI due to acute STEMI as compared with BMS or DES in the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON38630

Source
ToetsingOnline

Brief title
Master II study

Condition

- Myocardial disorders

Synonym
acute ST elevation myocardial infarction (STEMI)

Research involving
Human

Sponsors and support

Primary sponsor: InspireMD, Inc.
Source(s) of monetary or material Support: Inspire MD

Intervention

Keyword: Acute Myocardial Infarction, Randomised, Stent

Outcome measures

Primary outcome

The primary efficacy endpoint is the rate of complete ST-segment resolution defined as percentage of subjects with >70% resolution of the sum of ST elevations in all affected ECG leads within 60-90 minutes of completion of the stent procedure, powered to demonstrate superiority of the MGuard* Prime Stent compared to the control arm.

The primary safety endpoint is a composite of all-cause death or recurrent target vessel myocardial infarction (TV re-MI) at 365 days post-procedure, powered to demonstrate non-inferiority of the MGuard* Prime Stent compared to the control arm.

Secondary outcome

1. Infarct size assessed by cardiac magnetic resonance imaging (MRI) (from the first 356 eligible, consecutively enrolled subjects with anterior MI and proximal or mid LAD infarct vessel, at MRI-designated centers), with follow-up MRI conducted at 5 ± 2 days(range 3-7 days), powered for superiority
2. In-stent late lumen loss (LLL) (from the first 200 eligible, consecutively enrolled subjects at angiographic and IVUS follow-up designated centers stratified to intent to treat with BMS, and treated with the MGuardTM Prime or with BMS (if randomized to the control arm), as measured by quantitative coronary angiography [QCA] at 13 months), powered for non-inferiority

3. Procedural assessment of the coronary flow:

a. TIMI flow grade

b. Corrected TIMI frame count

c. Myocardial blush grade

d. Intra-procedural thrombotic events (IPTE)

4. Major Adverse Cardiac Events (MACE): defined as the composite of cardiac death, re-MI, or clinically-driven target lesion revascularization (TLR) at 30 days, 6, and 12 months

5. Composite endpoint of all-cause death or TV re-MI at 30 days and 6 months

6. Target vessel failure (TVF), defined as the composite of all-cause death, TV re-MI, or clinically-driven target vessel revascularization (TVR) at 30 days, 6 months and 12 months

7. Target lesion failure (TLF) defined as the composite of cardiac death, target vessel re-MI, or clinically-driven TLR at 30 days, 6, and 12 months

8. Cardiovascular Death or TV-re-MI at 30 days, 6, and 12 months

9. Rates for each component of the MACE, TVF and TLF composite endpoints reported at 30 days, 6, and 12 months

10. Acute Success Rates:

a. Device Success: Attainment of < 30% final residual stenosis of the target lesion using only the assigned stent.

b. Lesion Success: Attainment of < 30% final residual stenosis of the target lesion using any percutaneous method.

c. Procedure Success: Attainment of < 30% final residual stenosis of the target lesion using only the assigned stent, TIMI flow

SECONDARY ENDPOINTS (CONT)

grade 3 and no in-hospital MACE.

11. Bleeding or vascular complications at discharge

12. Stent thrombosis at 30 days, 6 and 12 months (ARC definition)

a. Definite stent thrombosis

b. Probable stent thrombosis

c. Definite or probable stent thrombosis

13. Angiographic Endpoints at 13-months by QCA, in patients enrolled in the angiographic follow-up substudy

a. In-stent and in-segment (within the 5 mm margins proximal and distal to stent)

- Percent diameter stenosis (%DS)

- Late loss

- Binary restenosis (stenosis of > 50% of the reference vessel diameter)

- Minimum lumen diameter (MLD)

14. IVUS Endpoints at 13-months, in patients enrolled in the angiographic and IVUS follow-up substudy

a. In-stent percent volume obstruction (%VO)

b. Neointimal hyperplasia (NIH) volume

c. Incomplete stent apposition

15. MRI Endpoints at 5-days, in patients enrolled in the cardiac MRI follow-up

substudy

a. Microvascular obstruction (MVO)

b. LV ejection fraction (LVEF)

c. Left ventricular (LV) end-systolic and end-diastolic volumes

d. Area at risk

Study description

Background summary

A heart attack is also known as a "myocardial infarction" (MI). A heart attack occurs when there is a blockage of blood flow in one or more of the coronary blood vessels (arteries) that supply blood to the heart muscle. A heart attack can occur when coronary arteries become blocked due to coronary artery disease (CAD). This blockage is due to a build-up of fat-like deposits (plaque) on the artery walls. This process is called atherosclerosis.
PCI is a treatment procedure that enlarges narrowed coronary arteries without performing surgery.
*Balloon catheter angioplasty: A small balloon is placed in the narrowed area of the artery and inflated with liquid. This pushes the plaque (blockage) to the sides of the artery where it remains. This technique restores the opening of the artery. The cardiologist removes the balloon at the end of the procedure. This procedure is often used in combination with a stent.

*Stent: The cardiologist places a small, hollow metal (mesh) tube called a *stent* in the artery to keep it open following a balloon angioplasty. This technique prevents constriction or closing of the artery during and after the procedure.

During stent placement, distal embolization often occurs. Small thrombus material will clod within the micovasculature and hamperes the restoration of the coronary blood flow.
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Study objective

The objective of this study is to evaluate the safety and efficacy of the MGuard* Prime stent in the treatment of de novo stenotic lesions in coronary arteries in patients undergoing primary PCI due to acute STEMI as compared with BMS or DES in the control arm. The MGuard* Prime stent has a fiber mesh that

traps the thrombus material between the stent and the vessel wall, preventing distal embolization,

Study design

Prospective , multicentre, randomised (1:1) clinical evaluation.
Total enrollment of 1114 subjects (557 in the MGuard* Prime System group and 557 in the control group), at up to 70 sites worldwide (a minimum of 40% US sites will be included). A minimum of 40% of the total enrollment will be from US sites. A maximum of 150 subjects will be enrolled at any one site.

Intervention

stenting with MGuard prime stent or a control DES or BMS

Study burden and risks

The subjects would also be subjected to most of the risks, even if they would not participate in the trial.
Subjects undergo a repeat coronar angigraphy at 13 months with IVUS. A coronar angigraphy has a know low risk this will take place in day treatment.
A small group of patients will have a MRI 3-7 days after the procedure; this can be experienced as uncomfortable by the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

General Inclusion Criteria
1. Subject is * 18 years of age.
2. Subject is experiencing clinical symptoms consistent with acute myocardial infarction (AMI) of >30 minutes and *12 hours in duration.
3. ST elevation *2 mm per lead in *2 contiguous leads is present in one ECG prior to consent.
4. Subject agrees to all required follow-up procedures and visits.
5. Subject provides written, informed consent.;Angiographic Inclusion Criteria
1. The target lesion is a de novo lesion in a native coronary artery.
2. Based on coronary anatomy, PCI is indicated for the culprit lesion with anticipated use of stenting.
3. The reference vessel diameter (RVD) of the infarct lesion is 2.75-4.0 mm by visual assessment, assessed either at baseline (if direct stenting is planned), or after pre-dilatation or thrombus aspiration (if direct stenting is not planned).
4. The entire lesion length requiring treatment is *24 mm (able to be covered by a single study stent), assessed either at baseline (if direct stenting is planned), or after pre-dilatation or thrombus aspiration (if direct stenting is not planned)
5. TIMI flow of 2/3 is present prior to randomization (in case of baseline TIMI flow 0/1, blood flow must be restored).

Exclusion criteria

General Exclusion Criteria
1. Left bundle branch block (LBBB), paced rhythm, or other ECG abnormality interfering with assessment of ST-segment.
2. Currently enrolled in another investigational device or drug trial that has not completed the primary endpoint or that clinically interferes with the current study endpoints.
3. A previous coronary interventional procedure of any kind within 30 days prior to the procedure.
4. Female patients of childbearing potential.
5. Subject undergoing cardiopulmonary resuscitation (patients in whom cardiopulmonary resuscitation was successfully performed and in whom normal mental status was achieved,

may be enrolled).
6. Cardiogenic shock (SBP <80 mmHg for >30 minutes, or requiring IV pressors or intra-aortic balloon bump (IABP) or other hemodynamic support device for hypotension).
7. The subject requires a staged procedure of the target vessel (including branches) within 12 months or of any non-target vessel within 7 days post-procedure.
8. The target lesion requires treatment with a device other than PTCA prior to stent placement (such as, but not limited to excimer laser, rotational atherectomy, etc.). Manual thrombus aspiration may be used per operator discretion, but rheolytic thrombectomy is only permitted for procedural complications after randomization.
9. Prior administration of thrombolytic therapy for the current admission
10. Co-morbid condition(s) that could limit the subject*s ability to participate in the trial or to comply with follow-up requirements, or impact the scientific integrity of the trial.
11. Concurrent medical condition with a life expectancy of less than 12 months.
12. History of cerebrovascular accident or transient ischemic attack within the last 6 months, or any permanent neurologic deficit
13. Prior intracranial bleed at any time, or known intracranial pathology (e.g. tumor, arteriovenous malformation, or aneurysm).
14. Active or recent site of major bleeding within 6 months.
15. History of bleeding diathesis or coagulopathy or inability to accept blood transfusions.
16. Known hypersensitivity or contraindication to either i) aspirin, or heparin and bivalirudin; or ii) clopidogrel , ticlopidine, prasugrel and ticagrelor; or iii) cobalt or nickel; or iv) contrast media, which cannot be adequately pre-medicated (prior anaphylaxis, however, is an absolute contraindication to enrollment).
17. Known serum creatinine level >2.5 mg/dl, hemoglobin <10 g/dL or platelet count <150,000 for the present admission or within 7 days prior to index procedure, if available. NOTE: Baseline labs do not have to be available to consent patient. If laboratory results become available only after randomization, and do not meet inclusion and exclusion criteria, the patient will not be de-registered from the study.
18. Surgery planned or any other reason necessitating discontinuation of dual anti-platelet therapy (aspirin and an ADP antagonist) within 12 months
19. Aortic dissection or mechanical complication of STEMI (papillary muscle rupture, ventricular septal defect or free wall rupture with or without pseudoaneurysm) identified by echocardiography or other means;Angiographic Exclusion Criteria
1. Unprotected left main stenosis *50%.
2. Multi-vessel intervention required during the index procedure.
3. Excessive tortuosity, calcification or diffuse distal disease is present either proximal to, at or distal to the target lesion making it unlikely that the study stent is unable to reach or cross the target lesion.
4. A non-infarct lesion with stenosis *50% is present in the target vessel (including its branches)
5. Target lesion is a bifurcation with a side branch *2.0 mm in diameter.
6. Target lesion at the site of or within a vessel with a previously implanted stent
7. Target lesion is within a bypass graft conduit, or can only be reached by passing the study stent through a bypass graft conduit
8. In the Investigator*s opinion the lesion/vessel is unsuitable for treatment with the study stent for any reason.
9. The lesion requires use of atherectomy, thrombectomy (not including manual thrombus

aspiration catheters), laser devices, or proximal or distal embolic protection devices prior to randomization.
10. Aortic dissection or mechanical complication of STEMI (papillary muscle rupture, ventricular septal defect or free wall rupture with or without pseudoaneurysm) identified by left ventriculography
Cardiac MRI Sub-study Exclusion Criteria (Only Applicable to Subjects Enrolled in the Cardiac MRI Sub-study)
1. Planned staged procedure prior to the MRI test.
2. A cardiac pacemaker or implantable defibrillator.
3. Non-MRI-compatible aneurysm clip.
4. Neural stimulator (e.g., TENS-Unit).
5. Any implanted or magnetically activated device (e.g., insulin pump).
6. Any type of non-MRI-compatible metallic ear implant.
7. Metal shavings in the orbits.
8. Any metallic foreign body, shrapnel, or bullet in a location which the physician feels would present a risk to the subject.
9. Any history indicating contraindication to MRI, including claustrophobia or allergy to gadolinium.
10. Inability to follow breathhold instructions or to maintain a breathhold for >15 seconds.
11. Irregular cardiac rhythm not expected to resolve after treatment of the acute cardiac condition (e.g., chronic atrial fibrillation).
12. Known hypersensitivity or contraindication to gadolinium contrast.
13. Impaired renal function (creatinine clearance <30 ml/min/1.73m2 [or <51.99 cc/min estimated with the Cockcroft-Gault formula]) or on dialysis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2013

Enrollment:	110
Type:	Actual

Medical products/devices used

Generic name:	M Guard stent/a commercial available BMS or DES (control)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01869738
CCMO	NL44890.018.13