Envast* thrombectomy device as adjunctive reperfusion modality in ST-segment elevation myocardial infarction

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To assess the safety and effectiveness of enVast coronary thrombectomy system thrombectomy as an adjunctive measure to conventional intervention as compared to conventional intervention in ST-segment elevation myocardial infarction (STEMI) patients...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON56525

Source
ToetsingOnline

Brief title
Nature Study

Condition

- Coronary artery disorders

Synonym
Occlusive thrombus complicating a ruptured or eroded atherosclerotic plaque

Research involving
Human

Sponsors and support

Primary sponsor: Vesalio
Source(s) of monetary or material Support: Vesalio;LCC

Intervention

Keyword: EnVast, PCI, STEMI, Thrombectomy

Outcome measures

Primary outcome

the size of the infarct as assessed by measurement of CK-MB. Blood samples will be obtained at admission and repeatedly over Days 1, 2, and 3. The area under the curve (AUC) for creatine kinase MB (CK-MB, expressed in ng/mL), will be measured in each subject.

Secondary outcome

Other clinically important endpoints include, but are not limited to:

• Infarct size, salvage index, microvascular obstruction, LV volumes and intramyocardial hemorrhage as measured by MRI.

• AUC for CK and hsTroponin T.

• The cumulative ST-segment deviation and residual ST-segment elevation resolution (calculated as the sum in mm of any ST-elevation and depression) to be measured immediately after the end of intervention and 90 minutes thereafter.

• TIMI flow, Corrected TIMI frame count and myocardial blush grade at the end of the procedure

• Left ventricular ejection fraction (LVEF), and LV volumes will be collected at day 3 and 5±2 months with MRI and at discharge and 12 months with transthoracic echocardiography, and they will be assessed by the core lab

• Kinetics of B-type natriuretic peptide during index hospitalization

• Histopathological evaluation of the retrived thrombotic material

The primary safety endpoint is MACE at Day 3 defined as cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke.

Serious adverse events (SAEs) throughout the 1-year follow-up will be described according to severity and to their relationship with the study device and procedure. Descriptive statistics (N, mean, median, SD, minimum and maximum values, where applicable) will be used to characterize safety parameters.

Other important safety endpoints will include:

• The composite of cardiovascular death, MI, and any cerebrovascular accident, including transient ischemic attack or stroke

• Death from cardiovascular causes

• Definite or probable stent thrombosis

• New onset cardiogenic shock requiring inotropes or mechanical assist device

• Myocardial infarction

• Stroke or transient ischemic attack

• Bleeding events (access site or non-access site related) according to the BARC classification.

• Rehospitalization for heart failure, resuscitated cardiac arrest or implantable cardioverter-defibrillator (ICD) implantation at follow-up.

• Bailout use of parenteral anti-platelet agents (GPI or cangrelor) defined as any use during or after the procedure in patients in whom no intention to use a parenteral anti-platelet agent was declared at the time of randomization.

• Any urgent or non-urgent target vessel revascularization

Study description

Background summary

In this study, we look at the safety and effectiveness of the medical device called enVast*.
This is a stent that can expand in the blood vessel of the heart, but can also be removed again (stent retriever).
This is used to remove blood clots from the heart vessels.
In some people with a heart attack, especially acute ST-segment elevation myocardial infarction (STEMI), the clogged blood vessel also contains a blood clot.
Usually an attempt is made to partially resolve this by sucking out the clot, with medication or to do nothing.
Another option is to use a stent retriever, which the cardiologist can use to remove the clot.
The doctor then tries to pull the clot out of the blood vessel and restore blood flow.
The study was designed to compare enVast* with standard treatments.

Study objective

To assess the safety and effectiveness of enVast coronary thrombectomy system thrombectomy as an adjunctive measure to conventional intervention as compared to conventional intervention in ST-segment elevation myocardial infarction (STEMI) patients with large thrombus burden undergoing primary percutaneous coronary intervention.

Study design

A prospective, randomized, study with one-year follow-up, designed to assess the safety and effectiveness of thrombus removal with the enVast coronary thrombectomy systems in STEMI patients.

Intervention

Subjects will be treated according to the treatment arm to which they have been assigned (either the thrombectomy arm of the enVast Coronary Thrombectomy System or the conventional treatment arm).

In the conventional treatment arm, treatment strategies may include balloon angioplasty, manual aspiration thrombectomy, and/or coronary stenting. The use of intravascular imaging modalities, including intravascular ultrasonography or optical coherence tomography, is permissible at any stage of the intervention according to institutional practice.

In the thrombectomy arm of the enVast Coronary Thrombectomy System, up to 3 attempts are made to remove a thrombus with the enVast before proceeding to treatment with conventional methods. The use of intravascular imaging modalities, including intravascular ultrasonography or optical coherence tomography, is permissible at any stage of the intervention according to institutional practice.

Study burden and risks

The anticipated adverse events associated with the cardiac thrombectomy procedure in this study include events reported in literature related to removal of clots, events identified in the risk and hazard analyses, and events associated with percutaneous interventions. All of these represent the risks associated with participation in the trial.

Potential device malfunctions and potential user errors have been identified in the Hazard Analysis and Failure Modes and Effects Analysis exercises conducted in accordance with ISO 14971. These are technical complications that may occur with the devices. Mitigating steps to address each of the potential device malfunctions and potential user errors have been implemented to reduce the risks as low as possible. No residual risks remain that are higher than the risks associated with the use of currently available conventional cardiac mapping and ablation tools.

Overall potential patient benefits include revascularization of occluded target vessel and preservation of function post-STEMI. Potential risks include adverse events and potential device malfunctions. Potential user errors are similar to those associated with other commercially available thrombectomy devices.

Based on a review of the potential benefits and the clinical need along with the residual risks identified through the completion of risk management activities to date, the overall residual risk is considered appropriate for the clinical benefits.

Test results from routinely performed standard of care assessments in STEMI management may be used throughout the study duration of 12 months per subject

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

1. Age >=18 years
2. Chest pain for >20 min with an electrocardiographic ST-segment elevation >=1 mm in two or more contiguous electrocardiogram (ECG) leads or an infero-lateral myocardial infarction (MI) with ST segment depression of >=1 mm in >=2 of leads V1-3 with a positive terminal T wave.
3. TIMI Thrombus Grade >= 3 in the infarct related artery. In cases where TIMI Thrombus Grade is equal to 5 (i.e. TIMI 0 flow in the infarcted artery), TIMI Thrombus Grade of at least 3 has to be re-confirmed with AWI. Patients showing TIMI Thrombus Grade of less than 3 upon AWI are no longer eligible for randomization.
4. Start of intervention within 8 h of symptom onset
5. Deferred consent after intervention signed by capable subject, signed by legal representative in case of incapable subject (subject remains included if deferred post-interventional consent was not signed before death).

Exclusion criteria

1. Unconscious patients
2. Infarct related artery diameter, at visual assessment, smaller than 2.5 mm

3. Presence of severely calcified plaque(s) proximal to or at the site of the culprit lesion(s)
4. Presence of extreme vessel tortuosity proximal to or at the site of the culprit lesion(s)
5. Women of childbearing potential (e.g. below 55 years of age, who have not undergone tubal ligation, ovariectomy or hysterectomy)
6. Stent thrombosis as culprit lesion
7. Previous myocardial infarction in the same territory (i.e. same target vessel).
8. Participation in another interventional clinical trial

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:	Recruiting
Start date (anticipated):	25-09-2024
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Envast
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	07-12-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-09-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT04969471
CCMO	NL84467.100.23