FLowTriever All-Comer Registry for Patient Safety and Hemodynamics (FLASH)

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The primary study objective is to evaluate the safety and effectiveness of the FlowTriever System for use in the removal of emboli from the pulmonary arteries in the treatment of acute pulmonary embolism (PE). The use of the device will be assessed...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Pulmonary vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON51566

Source
ToetsingOnline

Brief title
FLASH study

Condition

- Pulmonary vascular disorders
- Vascular therapeutic procedures
- Embolism and thrombosis

Synonym
Pulmonary embolism; Lung blood clot

Research involving
Human

Sponsors and support

Primary sponsor: Inari Medical Europe GmbH

Source(s) of monetary or material Support: De opdrachtgever;Inari Medical Europe GmbH;financiert de studie.

Intervention

Keyword: Catheter-directed, FlowTriever system, Pulmonary Embolism, Thrombolysis

Outcome measures

Primary outcome

The primary endpoint is the rate of Major Adverse Events (MAE). MAEs are

defined as a composite, when one or more of the following events occur:

• Device-related mortality through 48 hours after the index procedure, or

• Major bleeding through 48 hours after the index procedure, or

• Intra-procedural device or procedure-related adverse events, including:

o Clinical deterioration defined by hemodynamic or respiratory worsening, or o

Device-related pulmonary vascular injury, or

o Device-related cardiac injury

Secondary outcome

Secondary Safety Endpoints:

• Individual components of the MAE composite endpoint

• Major access-site complications requiring open surgical or endovascular

intervention or blood transfusion

• All-cause mortality through 30 days

• Device-related serious adverse events within 30 days

Secondary Effectiveness Endpoints:

• Reduction in pulmonary artery pressures during the procedure;

• Hemodynamic improvements during the procedure, including cardiac index (CI) and stroke volume index (SVI), right ventricular stroke work index (RVSWI), pulmonary artery pulsatility index (PAPi) and total pulmonary vascular resistance (TPVR)

• Reduction in right-ventricular/left-ventricular (RV/LV) ratio from baseline to 30 days and 6 months; as measured by echocardiography

Utility Measures:

• Fluoroscopy time

• Contrast used

• Thrombectomy time

• Estimated blood loss during the index procedure

• Length of intensive care unit stay, if any

• Length of total hospital stay

Study description

Background summary

Pulmonary embolism (PE) occurs when venous bloot clots (thrombi) travel from the peripheral veins, through the heart, and lodge in the lung (pulmonary) arterial circulation. The emboli arise from peripheral locations, usually the large deep veins of the leg and pelvis, but sometimes from the large veins of the upper extremities. While small PE may remain asymptomatic and go unnoticed, larger emboli may result in significant pulmonary artery obstruction, right heart decompensation, and mortality. Some PE are immediately fatal, particularly large PE that lodge at the branching of the main pulmonary artery; the so-called *saddle embolus.* On the other hand, PE may occur in a repeated fashion, often over months or even years, eventually resulting in a syndrome known as chronic thromboembolic pulmonary hypertension ("CTEPH"). Massive PE is defined as when a patient presents with shock from acute right ventricular

decompensation. Early, definitive treatment is necessary to prevent the rapid, downhill spiral that culminates in a patient*s death.

Anticoagulation with the removal of the occluding pulmonary artery thrombus is indicated, either by medication (pharmacologic), mechanical means, or a combination of both. In certain cases, open surgical pulmonary embolectomy and even extracorporeal membrane oxygenation (ECMO) may be necessary. Fortunately, massive pulmonary embolism occurs in less than 10% of cases.

While treatment of high-risk and low-risk patients ("massive PE" and "small PE") is clear, there is scant data on which to base therapeutic decisions for the intermediate-risk group. There has been recent enthusiasm for endovascular interventional treatment modalities, however, utilizing catheter-directed thrombolysis, ultrasound-accelerated thrombolysis, or mechanical thrombectomy.

Study objective

The primary study objective is to evaluate the safety and effectiveness of the FlowTriever System for use in the removal of emboli from the pulmonary arteries in the treatment of acute pulmonary embolism (PE). The use of the device will be assessed in a real-world population, with eligibility criteria that closely approximate its use in clinical practice.

Study design

The FLASH Registry is a prospective, single-arm, multicenter study of the FlowTriever System for intermediate-risk (submassive) and high-risk (massive) PE.

Study burden and risks

The study consists solely of collecting specific data for research purposes. As a result, the risks to subjects participating in the study are no different than for patients treated with the FlowTriever outside the study context. Study activities that fall outside standard care will require some extra time from 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

1. Age >= 18 years
2. Clinical signs and symptoms consistent with acute pulmonary embolism (PE)
3. Echo, CTPA, or pulmonary angiographic evidence of proximal filling defect in at least one main or lobar pulmonary artery
4. Scheduled for PE treatment with the FlowTriever System per the Investigator*s discretion

Exclusion criteria

1. Unable to anticoagulate with heparin or alternative
2. Diagnosed with a minor PE with less than a 0.9 RV/LV ratio
3. Known sensitivity to radiographic contrast agents that, in the Investigator*s opinion, cannot be adequately pre-treated
4. Imaging evidence or other evidence that suggests, in the opinion of the Investigator, the patient is not appropriate for mechanical thrombectomy intervention (e.g., inability to navigate to target location or predominately chronic clot)
5. Life expectancy < 30 days, as determined by the Investigator
6. Current participation in another investigational drug or device treatment

study that, in the investigator*s opinion, would interfere with participation in this study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	FlowTriever System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-10-2022
Application type:	First submission
Review commission:	METC NedMec

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	NCT03761173
CCMO	NL81709.041.22

Study results

Actual enrolment: 0

Summary results
Trial never started