Prospective randomized multicenter study comparing immediate multivessel revascularization by PCI versus culprit lesion PCI with staged non-culprit lesion revascularization in patients with acute myocardial infarction complicated by cardiogenic shock

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To examine whether culprit lesion only percutaneous coronary intervention (PCI) with subsequent staged revascularization is beneficial over immediate multivessel revascularization by PCI for patients with cardiogenic shock complicating acute...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON45167

Source
ToetsingOnline

Brief title
CULPRIT-SHOCK

Condition

- Coronary artery disorders

Synonym
cardiac disease, Coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: University of Lubeck
Source(s) of monetary or material Support: FP7-HEALTH-2013-INNOVATION-1

Intervention

Keyword: Cardiogenic, Myocardial Infarction, Percutaneous Coronary Intervention, Shock, Treatment Outcome

Outcome measures

Primary outcome

30-day mortality and/or severe renal failure requiring renal replacement

therapy [Time Frame: 30 days]

Secondary outcome

30-day mortality [Time Frame: 30 days]

Requirement of renal replacement therapy [Time Frame: 30 days]

Time to hemodynamic stabilization [Time Frame: 30 days]

Duration of catecholamine therapy [Time Frame: 30 days]

Serial creatinine-level creatinine-clearance [Time Frame: 30 days]

Length of ICU-stay [Time Frame: 30 days]

Serial intensive care scoring (SAPS-II score) until stabilization [Time Frame:

30 days]

Requirement and length of mechanical ventilation [Time Frame: 30 days]

All-cause death within 12 months follow-up [Time Frame: 12 months]

Recurrent infarction within 30-days follow-up [Time Frame: 30 days]

Death or recurrent infarction at 12 months follow-up [Time Frame: 12 months]

Rehospitalization for congestive heart failure within 12 months follow-up [

Time Frame: 12 months]

Death/recurrent infarction/rehospitalization for congestive heart failure

within 12 months [Time Frame: 12 months]

Need for repeat revascularization (PCI and/or CABG) within 12 months follow-up

[Time Frame: 12 months]

Peak creatine kinase level during hospital stay [Time Frame: 30 days]

Quality of life at 6 and 12 months assessed using Euroqol 5D (EQ-5D) [Time

Frame: 12 months]

Maximum creatine kinase-MB level [Time Frame: 30 days]

Maximum troponin level [Time Frame: 30 days]

Recurrent infarction within 12 months follow-up [Time Frame: 12 months]

Study description

Background summary

Despite aggressive treatment modalities such as PCI as well as mechanical and inotropic support, mortality of cardiogenic shock complicating acute myocardial infarction remains at a very high level with mortality rates between 45-70%.The majority of patients in cardiogenic shock presents with multivessel coronary artery disease and the mortality of these patients is higher than mortality in patients with single vessel disease.From a pathophysiological standpoint it might be beneficial to reperfuse all relevant coronary arteries with significant coronary artery stenoses in addition to the culprit lesion to improve myocardial perfusion. On the other hand immediate multivessel PCI might pose additional risk for the patients. However, there are no randomized clinical trials assessing the optimal reperfusion strategy.

Study objective

To examine whether culprit lesion only percutaneous coronary intervention (PCI) with subsequent staged revascularization is beneficial over immediate multivessel revascularization by PCI for patients with cardiogenic shock complicating acute myocardial infarction with respect to 30-day mortality and/or severe renal failure requiring renal replacement therapy.

Study design

Prospective, controlled, international, multicenter, randomized, open-label

Intervention

Immediate multivessel PCI

Culprit lesion only PCI

Study burden and risks

It may also be hypothesized that multivessel PCI may reduce the subsequent adverse events after primary PCI by preventing the incidence of both early and late recurrent ischemia in the non-infarct related lesions, which in turn could obviate the need for recurrent procedures, reducing overall ischemic burden and attenuating the incidence of unpredictable subsequent cardiac events. Complete revascularization at the time of infarction may also reduce overall hospital stay and total cost of care. On the other hand, major concern exists regarding the risks of prolonged interventional procedures with higher amounts of contrast dye and the hypothetical risk of stent thrombosis in non-culprit lesions when stent implantation has taken place in the thrombogenic milieu of acute myocardial infarction. A successful primary PCI of the infarct related artery and a complicated or unsuccessful PCI to the non-infarct related artery would be potentially hazardous, especially in the setting of cardiogenic shock

The risks associated with participation in the study are equivalent of those associated with standard (primary) PCI in patients with cardiogenic shock. The patient burden consists of the possibility that patients who are deferred for complete revascularization need to be scheduled for additional percutaneous coronary intervention if significant signs of cardiac ischemia persist, additionally the patient will be contacted by telephone at 30 days, 6 months and 12 months follow up.

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

Cardiogenic shock complicating acute myocardial infarction (STEMI or NSTEMI) with obligatory:;1. Planned early revascularization by PCI;2. Multivessel coronary artery disease defined as >70% stenosis in at least 2 major
vessels (>=2 mm diameter) with identifiable culprit lesion;3. a Systolic blood pressure <90 mmHg for >30 min or
b catecholamines required to maintain pressure >90 mmHg during systole and;4. Signs of pulmonary congestion;5. Signs of impaired organ perfusion with at least one of the following criteria
a) Altered mental status
b) Cold, clammy skin and extremities
c) Oliguria with urine output <30 ml/h
d) Serum-lactate >2.0 mmol/l;6. Informed consent

Exclusion criteria

1. Resuscitation >30 minutes;2. No intrinsic heart action;3. Cerebral deficit with fixed dilated pupils (not drug-induced);4. Need for primary urgent bypass surgery (to be determined after diagnostic angiography);5. Single vessel disease;6. Mechanical cause of cardiogenic shock;7. Onset of shock >12 h;8. Massive lung emboli;9. Age >90 years;10. Shock of other cause (bradycardia, sepsis, hypovolemia, etc.);11. Other severe concomitant disease with limited life expectancy <6 months;12. Pregnancy;13. Known severe renal insufficiency (creatinine clearance <30 ml/kg)

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:	Will not start
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	05-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	08-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2017
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	NCT01927549
CCMO	NL47279.018.14