SAFETY AND FEASIBILITY OF INTRACORONARY HYPOTHERMIA IN ACUTE MYOCARDIAL INFARCTION (SINTAMI)

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To evaluate the feasibility and safety of selective intracoronary hypothermia in acute myocardial infarction

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

Summary

ID

NL-OMON42138

Source
ToetsingOnline

Brief title
SINTAMI

Condition

- Coronary artery disorders

Synonym
heart attack, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: geen financiering

Intervention

Keyword: intracoronary hypothermia, myocardial infarction

Outcome measures

Primary outcome

Feasibility

- Is the protocol easily performed by the operators

- Is a quick temperature drop achieved

- Is it possible to obtain a stable coronary temperature during 30 minutes.

Safety

- Is there a higher incidence of rhythm- or conductance disturbances compared

with the routine PCI procedure for myocardial infarction or is any other

unforeseen side effect observed.

Secondary outcome

Not applicable

Study description

Background summary

In acute myocardial infarction, early restoration of epicardial and myocardial blood flow is of paramount importance to limit infarction size and create optimum conditions for favourable long-term outcome.
Currently, restoration of epicardial blood flow is preferably obtained by primary percutaneous coronary intervention (PPCI). After opening the occluded artery, the reperfusion process itself also causes damage to the myocardium, the so called *reperfusion injury.* Therapeutic hypothermia, i.e. the cooling of damaged tissue, is thought to attenuate this reperfusion injury.

Animal studies have shown that the induction of hypothermia before reperfusion of an acute coronary occlusion reduces infarct size. Previous studies in humans, however, have not been able to confirm this effect, which is mainly believed due to the fact that therapeutic temperature was not reached before reperfusion in the majority of the patients. Furthermore, in these studies it was intended to induce whole body hypothermia, which may lead to systemic reactions such as shivering and an enhanced adrenergic state. We aimed to evaluate the safety and feasibility of rapidly induced intracoronary hypothermia by selective intracoronary infusion of cold saline before and after reperfusion in patients with acute myocardial infarction.

Study objective

To evaluate the feasibility and safety of selective intracoronary hypothermia in acute myocardial infarction

Study design

Pilot study in which the safety and feasibility of an intervention is evaluated.

Intervention

Additional to the routine percutaneous coronary interrvention, the procedures for the study include:
- insertion of temperature wire (PW)
- Insertion of over-the-wire balloon (OTW)
- Inflating balloon (4 atm.)
- removal of guide wire
- start hypothermia (10 min.):
- induction: NaCl room temperature degrees Celsius, at a flow rate of 40 ml/min.,
- Continuous monitoring of distal coronary temperature by the PW
- Deflating balloon after 10 min. of hypothermia during occlusion
Reperfusion occurs, but no stent is placed yet
- Continuing hypothermia (10 min): NaCl room temperature degrees Celsius, 40 ml/min. on an open coronary artery

Study burden and risks

The initial procedure will be the emergent coronary angiography identical to the first part of a regular PPCI and implantation of stents. There are no associated risks with that part of the procedure.
In patients eligible for the study, thereafter, the additional intracoronary hypothermia is administered with measurements of physiologic parameters. Equipment and drugs used in this part of the exam are not different from

standard equipment. The procedure is prolonged by 20 minutes. There is a moderate load of saline, i.e. 1000 a 1200 ml. We do not anticipate any adverse effect.
Several animal studies indicated no risks of moderate hypothermia.[6-8] Additionally, there were even benefits observed concerning safety such as less arrhythmia.[5]
In human studies no additional risks, such as hemodynamic instability or arrhythmias, were noted during systemic hypothermia.[9-12] All the clinical studies used a cooling method in which the whole body was cooled off. We postulate that these cooling methods carry much higher risks and patient discomfort such as shivering compared to the selective intracoronary hypothermia in which systemic hypothermia symptoms probably will not occur.
Finally and importantly, in the Catharina hospital Eindhoven we already performed several studies in which saline at room temperature was infused intracoronary in a similar rate as in this study, both in stable patient. (n = 88) [13] and patients with acute myocardial infarction (n=20). (Wijnbergen et al. study performed presently METC nr M11-1158) Except rapidly transient conductive disturbances in three patients, not any adverse effect was noted.

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

Patients will be eligible for this study when they are admitted for acute ST elevation myocardial infarction with a total ST-segment deviation of more than 5 mm and presenting within 6 hours after onset of complaints.
Patients should have a TIMI 0, 1 or 2 flow in the infarction related artery.
If these patients are hemodynamically stable and in an acceptable clinical condition, informed consent will be asked to participate in this study.

Exclusion criteria

• Age < 18 year
• Cardiogenic shock or pre-shock
• Poor clinical condition with concomitant inconvenience like repeated vomiting, severe chest pain or elsewise according to the judgement of the treating interventionalist.
• Patients with previous myocardial infarction in the culprit area of with previous bypass surgery
• Tortuous coronary arteries
• Complex or long-lasting primary PCI expected
• Severe concomitant disease or conditions with a life expectancy of less than one year
• Inability to understand and give informed consent either in first instance on the table or in second instance on the coronary care unit.
• Other known myocardial diseases, such as moderate or severe left ventricular hypertrophy or cardiomyopathy
• Pregnancy
• Mobitz II block, trifascicular block, or total AV block
• Patients in whom no access to the coronary circulation can be obtained by the femoral artery or in whom femoral access was problematic

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	11-08-2015
Application type:	First submission
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
CCMO	NL48766.060.14