# The safety and efficacy of implementing the PreHEART decision support tool by the Emergency Medical Service for patients with undifferentiated chest pain: a prospective randomized open blinded end-point study (PreHeart-3 study)

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27238

**Source**
Nationaal Trial Register

**Brief title**
PReHEART study

**Health condition**

Acute coronary syndrome
Non-st segment Elevated Myocardial Infarction
Undifferentiated chest pain

### Sponsors and support

**Primary sponsor:** none
**Source(s) of monetary or material Support:** none

## Intervention

## Outcome measures

### Primary outcome

Unexpected Serious Adverse Events (USAE) at 3 and 30 days from the index contact.

### Secondary outcome

* USAE at 6 months and 1 year from the index contact
* Unexpected Major Adverse Cardiac Event (UMACE) at 3 days, 30 days, 6 months and 1 year after index contact.
* Cumulative healthcare-related costs/resource
* Quality of life at 3 days, 30 days, 6 months and 1 year of the index contact evaluated through the EuroQol 5D-5D-5L

# Study description

### Background summary

Decisions on (non-)conveyance of patients are challenging for the ambulance personnel (emergency medical services [EMS]). The majority (>75%) of patients presenting with undifferentiated chest pain (or discomfort) is conveyed to the nearest hospital. Improving pre-hospital assessment of patients with undifferentiated chest pain may improve safety, optimize the efficacy of care, and reduce health-related costs.
Observational data in patients conveyed to the hospital suggests that our recently developed pre-hospital HEART (preHEART) risk score represents a reliable tool to identify individuals at very low risk (±38% of patients), low-intermediate (±5%) and very high risk (±7%) of severe cardiovascular pathology requiring urgent care. Whether adding this decision support tool in clinical practice to support the decision-making process on (non-)conveyance by the ambulance personnel is safe and more.

### Study objective

The PreHEART score supports EMS staff in their decision to convey a patient with undifferentiated chest pain and increases the non-conveyance up to 20%, which leads to fewer presentations to an ED.

### Study design

3 days, 3 and 12 month

**Intervention**

The PreHEART is available to a randomized patient whose risk of an ACS has been assessed. The decision to convey can be guided by the preHEART score which suggestion to non-convey for patients with a very low risk of ACS, or convey patients with intermediate risk to the nearest hospital, or convey a patient to a hospital with PCI facilities.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Adults with undifferentiated chest pain.

## Exclusion criteria

Communication barrier (e.g. language, understanding)
ST-segment elevation (electrocardiogram on scene is standard workup)
Any obvious etiology for the symptoms requiring direct treatment (e.g. trauma)
Being previously evaluated by ambulance personnel for the same complaint (already considered for participation)
High clinical suspicion of a life-threating condition (e.g. sudden death survivor, hypothermia, shock, aortic dissection, hypoxia or intoxication)
Cognitive impairment
End-stage renal disease
Pregnancy
Inability or unwillingness to provide informed consent
Not registered with a GP (huisarts)

COVID suspicion

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-04-2020 |
| Enrollment: | 5150 |
| Type: | Actual |

## IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**
Upon any reasonable and motivated request will be considered

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 12-07-2019 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL7866 |
| Other | METC UMCG : METC approval pending |

# Study results

**Summary results**
PreHEART development and validation study has been submitted