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)

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27238

Bron
Nationaal Trial Register

Verkorte titel
PReHEART study

Aandoening

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

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

3 days, 3 and 12 month

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

UMC Groningen
Dennis Sagel

0503616161

Wetenschappelijk

UMC Groningen
Dennis Sagel

0503616161

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adults with undifferentiated chest pain.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2020
Aantal proefpersonen:	5150
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
Upon any reasonable and motivated request will be considered

Ethische beoordeling

Positief advies

Datum:	12-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7866
Ander register	METC UMCG : METC approval pending

Resultaten

Samenvatting resultaten
PreHEART development and validation study has been submitted