RCT to assess In hospital 24 hour observation with telemetry of Syncope patients admitted to the Cardiac Emergency Room

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1) To determine if the 24 hour admission with TM can be omitted safely in the setting of CER for patients with low- and intermediate risk syncope (non-inferiority) 2) to determine the health care cost reduction (superiority), 3) additional...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51650

Source
ToetsingOnline

Brief title
SYNCOPE R.I.S.C. trial

Condition

- Other condition

Synonym
Syncope, T-LOC

Health condition

laag- intermediair risico syncope patienten

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac Emergency Care, Initial Evaluation, Risk, Syncope

Outcome measures

Primary outcome

Primary: (non-)fatal serious adverse events in both arms (non-inferiority)

Secondary outcome

Secondary: healthcare costs and hospital utilization (superiority), proportion

of additional diagnoses in both treatment arms after 24 hrs and 7 days of

ambulant holter monitoring and QoL during 1 month after presentation on ED.

Study description

Background summary

Syncope is very common and has a broad differential diagnosis. Guidelines on syncope recommend to apply guideline based syncope algorithm (SA) to identify low- / intermediate risk syncope patients and recommend to discharge these patients (class 1, level of evidence B). Nevertheless, these patients are still frequently admitted for 24 hour observation with telemetry (TM) on the Cardiac Emergency Room (CER). There seems to be an equipoise for both treatment strategy arms in current medical practice. A randomized controlled trial to compare the 24 hour observation including TM with immediate discharge has never been done on the CER.

Study objective

1) To determine if the 24 hour admission with TM can be omitted safely in the setting of CER for patients with low- and intermediate risk syncope (non-inferiority) 2) to determine the health care cost reduction (superiority),

3) additional diagnostic yield of both arms and 4) QoL after one moth follow up (SFS 12 and SFSQ).

Study design

multicenter prospective randomized controlled comparison of immediate discharge and admission for 24 hour observation with TM.

Study burden and risks

The study carries no risk. Both treatment strategy arms are already part of clinical practice and applied randomly by physicians on the CER to patients with low- / intermediate syncope. In this trial the guideline based SA will be part of routine care to all patients with suspected syncope in order to identify the eligible patients with low- / intermediate risk syncope. Participation burden is limited to questionnaires. The questionnaires relate to symptom burden, quality of life and health care costs/hospital utilization. We do not believe that the questionnaires are offensive to the study participants. Filling out these questionnaires does, however, cost time. Patients are able to schedule this as they like. Study participation has no benefit for their personal treatment. It has however the advantage that the study will help to improve syncope care. We believe that the lack of risk, the limited study burden and the possibility to terminate the study at any time, justifies the study in this patient group.

Contacts

Public
Academisch Medisch Centrum

1105 AZ 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

1105 AZ 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients with low risk- and intermediar risk syncope presented on the Cardiac Emergency Care, will be eligible for the study.

Exclusion criteria

(1) Those aged <18 years
(2) Those in whom syncope / transient loss of consciousness co-exisits with trauma or other serious condition identified in the CER (massive bleeding, pulmonary embolus) or any high-risk features upon assessment with guideline based SA (see appendix 2)
(3) Those with any other conditions then syncope / transient loss of consciousness for which admission is required (including social indication for admission, etc.)
(4) Contraindication for early discharge at the discretion of the responsible physician
(5) Those with a learning disability
(6) Those presenting with pre-syncope
(7) Those who are unwilling to provide informed consent (those will be asked to be enrolled for the SYNCOPE R.I.S.C - registry)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-11-2023
Enrollment:	640
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2024
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
CCMO	NL81736.018.22