Syncope algorithms in the emergency department with structured follow-up. How effective is a standardised approach at improving diagnostic yield, quality of life and decreasing health care costs? The SYNERGY study

Published: 20-12-2016
Last updated: 19-03-2025

We will conduct a multicentre trial to study the implementation of the ESC/EHRA syncope algorithms (SAs) in one university hospital & three regional hospitals. We will implement the SAs in both the ED (standardised triage system) as well as the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45663

Source
ToetsingOnline

Brief title
The SYNERGY study

Condition

- Other condition

Synonym
fainting, syncope

Health condition

syncope

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: algorithm , syncope

Outcome measures

Primary outcome

Proportion of patients with an accurate diagnosis (as determined by an expert

panel at 1 year follow-up)

Secondary outcome

Number of admissions because of syncope, time to diagnosis following ED

presentation, syncope recurrence, Healthcare and societal costs within 1 year

following ED presentation, number of syncope-related tests and consultations,

QoL

Study description

Background summary

Syncope is very common and has a broad differential diagnosis. The frequent failure to identify benign or malignant causes results in high costs. Syncope Algorithms (SAs) abroad have shown to improve diagnostic yield and reduced costs.

Study objective

We will conduct a multicentre trial to study the implementation of the ESC/EHRA

syncope algorithms (SAs) in one university hospital & three regional hospitals. We will implement the SAs in both the ED (standardised triage system) as well as the outpatient services (dedicated syncope facilities). We aim to compare cost-effectiveness of SAs to usual care.

Study design

Multicentre trial comparing the pre- and post-implementation period

Intervention

SA implementation has multiple components:
- ED triage resulting in admission, outpatient or GP referral
- Innovative multilingual communication system facilitating active patient participation to maximize the yield of history taking in syncope
- Structured outpatient evaluation

Study burden and risks

The study carries no risks. Study participants receive similar diagnostic work-up and treatment as those who are not willing to participate. Participation is limited to serial questionnaires. The questionnaires relate to symptom burden, quality of life and health care costs. 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 risks, the limited study burden and the possibility to terminate the study at any time, justifies the study in this patient group.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients at the emergency department because of suspected syncope

Exclusion criteria

(1) Those aged <18 years
(2) Those in whom a serious life threatening condition is identified in the ED (massive bleeding, pulmonary embolus)
(3) Those who attended any ED because of syncope in the previous year
(4) Those with a learning disability
(5) Those presenting with presyncope
(6) Those who already attented a tertiary syncope clinic

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2017
Enrollment:	550
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-12-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-04-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23988
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL58852.058.16
OMON	NL-OMON23988