Longterm outcome of patients with fainting spells at the emergency department. How effective is a standardised approach at improving the time to correct diagnosis, quality of life and decreasing healthcare costs?

No registrations found.

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

Summary

ID

NL-OMON23988

Source
Nationaal Trial Register

Brief title
The SYNERGY study

Health condition

Syncope, fainting spells, transient loss of consciousness. Wegraking, flauwvallen.

Sponsors and support

Primary sponsor: LUMC, neurology department. Prof. J.G. van Dijk/ Dr. R.D. Thijs.
Source(s) of monetary or material Support: ZonMW; the Netherlands Organisation for Health research and development.

Intervention

Outcome measures

Primary outcome

Proportion of cases with an accurate diagnosis (as determined by the expert panel at 1 year follow-up).

Secondary outcome

Quality of Life (SFS, EQ-5D-5L) during 1 year after ED presentation.

Number of syncope-related admissions

Healthcare costs within 1 year following ED presentation.

Time to a certain/highly likely diagnosis following ED presentation

Number of diagnostic tests performed

Number of syncope-related consultations (ED, outpatient & GP visits)

Proportion of cases with recurrent syncope

Syncope-related healthcare costs within 1 year following ED presentation.

Study description

Background summary

SUMMARY

Rationale

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.

Objective:

To determine the cost-effectiveness of SAs compared to usual care in those presenting with syncope at the ED

Study design:

Multicentre trial comparing the pre- and post-implementation period

SA implementation has multiple components:

- ED triage resulting in admission, outpatient or GP referral

- E-health system to maximize the yield of history taking in syncope

- Structured outpatient evaluation

Study population:

Syncope patients in the emergency department (ED) of 1 university hospital & 4 regional hospitals

Study intervention

Structured follow-up with questionnaires at baseline, 3, 6 and 12 months in two patient cohorts before and after SA implementation

Main study parameters/endpoints:

Primary: proportion of patients with an accurate diagnosis (as determined by an expert panel at 1 year follow-up)
Secondary: 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

Country: The Netherlands

Study objective

-

Study design

In both groups (usual care and SA implementation) patients will be asked to fill out questionnaires at baseline, 3, 6 and 12 months of follow-up. The questionnaires include a check-list to assess health care consumption, productivity, and QoL measures: Syncope

Functional Status (SFS) & EQ-5D-5L.

Intervention

Each emergency department will adopt the ESC/EHRA syncope algorithms including a standardized assessment of historical features, ECG, physical examination and orthostatic blood pressure measurements. Prior to implementation, an educational course will offered to all physicians involved in the ED management of syncope.

Usual syncope care at the emergency department. The inclusion of the control group will start prior to the implementation of the syncope algorithms at each hospital. Five hospitals will include patients (LUMC Leiden, Gelre ziekenhuis Apeldoorn, Rijnstate Arnhem, Maasstad ziekenhuis Rotterdam, Diaconessenhuis Utrecht)

Contacts

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Eligibility criteria

Inclusion criteria

All patients 18 years and older attending the ED for suspected syncope will be included.

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 who already attended the tertiary outpatient clinic “Syncope and autonomic disorders” in LUMC because of syncope and received a certain or highly likely diagnosis

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-01-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45663
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6129
NTR-old	NTR6268
CCMO	NL58852.058.16
OMON	NL-OMON45663

Study results