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?

Gepubliceerd: 11-01-2017 Laatst bijgewerkt: 19-03-2025

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

Samenvatting

ID

NL-OMON23988

Bron
Nationaal Trial Register

Verkorte titel
The SYNERGY study

Aandoening

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

Ondersteuning

Primaire sponsor: LUMC, neurology department. Prof. J.G. van Dijk/ Dr. R.D. Thijs.
Overige ondersteuning: ZonMW; the Netherlands Organisation for Health research and development.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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)

Contactpersonen

Publiek

LUMC Albinusfreef 2

M. Ghariq
Kamer J3-165

Leiden 2333 ZA
The Netherlands
-

Wetenschappelijk

LUMC Albinusfreef 2

M. Ghariq
Kamer J3-165

Leiden 2333 ZA
The Netherlands
-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

(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

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2017
Aantal proefpersonen:	550
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-01-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45663
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten