Implementation of Syncope Algorithms in the Dutch emergency departments: an interventional trial

Gepubliceerd: 07-08-2016 Laatst bijgewerkt: 13-12-2022

Implementation of Syncope Algorithms (SAs) in the Netherlands will increase diagnostic yield, avoid unnecessary admissions and improve quality of life (QoL) by offering timely diagnosis & treatment

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21713

Bron
NTR

Verkorte titel
SYNERGY trial

Aandoening

syncope, transient loss of consciousness, algorithm

Ondersteuning

Primaire sponsor: Leiden University Medical Centre
Overige ondersteuning: ZonMW 80-84300-98-72056

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

OBJECTIVE/ RESEARCH QUESTIONS

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.

HYPOTHESIS

Implementation of SAs in the Netherlands will increase diagnostic yield, avoid unnecessary admissions and improve quality of life (QoL) by offering timely diagnosis & treatment

STUDY DESIGN

Multicentre trial comparing the pre- and post-implementation period

STUDY POPULATION

Syncope patients in the emergency department (ED) of 1 university hospital & 3 regional hospitals

INTERVENTIONSA
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

OUTCOME MEASURES

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

SAMPLE SIZE CALCULATION/ DATA ANALYSIS

Based on a power of 0.8 and alpha of 0.05, we need to recruit 360 per group, i.e. 52% of all eligible syncope cases. We will conduct a multi-level analysis comparing the effects of the intervention while accounting for differences per study centre

COST-EFFECTIVENESS ANALYSIS (CEA) & BUDGET IMPACT ANALYSIS (BIA):

Trial-based cost-effectiveness analysis (diagnostic costs per accurate diagnosis), trial-based cost-utility analysis (societal cost per QALY), and cost calculator spreadsheet model (BIA)

Doel van het onderzoek

Implementation of Syncope Algorithms (SAs) in the Netherlands will increase diagnostic yield, avoid unnecessary admissions and improve quality of life (QoL) by offering timely diagnosis & treatment

Onderzoeksopzet

- Diagnostic accuracy: evaluation of medical files by an expert panel at 1-year follow-up

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

- QoL measures (SFS & EQ-SD-5L) at baseline, 3, 6 and 12 months follow-up.

Onderzoeksproduct en/of interventie

SA implementation has multiple components:

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Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Emergency department presentation becasuse of suspected syncope

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2017
Aantal proefpersonen:	720
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5880
NTR-old	NTR6053
Ander register	80-84300-98-72056 : ZonMW

Resultaten