Orthostatic related blood pressure changes in syncope patients in the emergency department

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29397

Source
Nationaal Trial Register

Health condition

Syncope. Orthostatic hypotension. Initial orthostatic hypotension. Reflexsyncope. Vasovagal reflexsyncope.
Syncope. Orthostatische hypotensie. Initiële orthostatische hypotensie. Reflexsyncope. Vasovagale reflexsyncope.

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The main study parameter at the initial evaluation in the ED is the difference between the proportion of correct working diagnosis made by the attending physician and by the investigator.

For the follow-up at the outpatient department the main study parameter is the difference in (pre-) syncope recurrence during the 1 year follow-up in comparison with the previous year.

Secondary outcome

The secondary study parameter for the initial evaluation in the EDis:

•The difference between the proportion of correct working diagnosis in the patients of group 1, before and after the evaluation with Nexfin.

The secondary study parameters for the follow-up at the outpatient department are:

•Quality of life after one year of follow-up

•Falls history of the past year in comparison with the follow-up year in patients >60 years

•The recovery to normalisation of the orthostatic blood pressure recovery patterns

•30 days mortality, one year mortality

Study description

Background summary

This study is part of standard care for syncope patients. A patient with syncope is a challenge for the attending physician at the emergency department. In order to find ways to improve the initial evaluation of syncope patients and to provide follow-up care at the outpatient department, this study was started, with an emphasis on the orthostatic blood pressure regulation patterns. The non-invasive continuous blood pressure measurement method (Nexfin) is increasingly used, but it isn't applied yet in daily practise. This study investigates the possible added value of Nexfin, next to a detailed (expert) history taking.

Study objective

Syncope is a frequent reason for referral in the emergency department (ED). Orthostatic hypotension (OH) is a common cause for syncope in the elderly population. Increasingly orthostatic blood pressure responses are measured by non-invasive continuous blood pressure measurement (Nexfin). However, the clinical implications of different blood pressure recovery patterns are not well determined yet. Measurement of the orthostatic blood pressure is part of the initial evaluation of syncope in the ED.The additional value of Nexfin in the initial evaluation and work-up of the syncope patient in the ED still needs to be investigated. Next to the different orthostatic blood pressure recovery patterns, different types of pathophysiological changes have been recognized in OH, respectively arteriolar,

venous and mixed. When taking the orthostatic blood pressure recovery patterns and the pathophysiological types into account, it is possible to come to a rational treatment. The effect of a directed treatment on the orthostatic blood pressure recovery patterns has not been studied yet.

The main objective of the study is to determine the diagnostic and prognostic added value of Nexfin in the initial evaluation of (pre-) syncope patients in the ED and the follow-up period. The secondary objective is to determine the effectiveness of therapeutic intervention in (pre-) syncope patients with and without abnormal blood pressure recovery patterns regarding recurrence of (pre-) syncope.

Study design

Correct working diagnosis will be determined after one year of follow up by an independent expert panel.
The recurrence of syncope complaints will be determined at the end of the follow up year.

Intervention

Keeping a diary about (pre)syncope complaints.
Questionnaires about quality of life (3x), and for 60+ patients: once a mini mental state examination and an Activities of Daily Living questionnaire (Barthel Index).

Contacts

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Eligibility criteria

Inclusion criteria

•The patient must be 18 years or older

•The reason for referral to the ED must be (pre-) syncope

•The patient must be able to stand for 5 minutes with little assistance

Exclusion criteria

•The patient is hemodynamically instable (with supine resting SBP <90 mmHg or DBP <50 mmHg)

•The patient needs immediate additional investigations/treatment

•The patient is psychologically, physically (due to any other illness) or cognitively unfit for participation in the study according to the opinion of the investigator

• The patient is geographically or otherwise inaccessible to follow up

•The patient is unwilling or unable to give informed consent

•When there are other reasons for transient loss of consciousness, which do not fit the definition of syncope, such as alcohol, illicit drugs, seizure, stroke/transient ischemic attack, head trauma or hypoglycemia

•Life expectancy <1 year

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2015
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42478
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5532
NTR-old	NTR5651
CCMO	NL53080.042.15
OMON	NL-OMON42478

Study results