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

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The main objective of the study is to determine the diagnostic and prognostic added value of careful history taking and Nexfin in the initial evaluation of (pre-) syncope patients in the ED and the follow-up period. The secondary objective is to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42478

Source
ToetsingOnline

Brief title
Orthostatic blood pressure

Condition

- Other condition
- Decreased and nonspecific blood pressure disorders and shock

Synonym
fainting, loss of consciusness

Health condition

Syncope

Research involving
Human

Sponsors and support

Primary sponsor: Acute interne geneeskunde
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Nexfin, Orthostatic blood pressure, Orthostatic hypotension, Syncope

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 parameters for the initial evaluation in the ED is:

• 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 of 60 years and older

• The recovery to normalisation of the orthostatic blood pressure recovery

patterns

• 30 days mortality, one year mortality

For all secondary study parameters from the follow-up there will be a sub

analysis between the group with Nexfin measurement and the blinded Nexfin

measurement.

Study description

Background summary

Orthostatic hypotension (OH), a sustained fall in blood pressure with standing, is caused by an excessive drop in the cardiac output and/or by an inadequate vasoconstriction mechanism. OH is associated with increased (cardiovascular) morbidity and mortality. It is relatively common in the elderly population and the prevalence increases with age and varies between the chosen populations. In community-dwelling elderly the prevalence is 6-30%, while the prevalence is up to 50% in nursing home residents.
Therefore adequate recognition of OH is crucial. According to the consensus definition, OH is a sustained drop of the systolic blood pressure of at least 20 mmHg and/or of the diastolic blood pressure of at least 10 mmHg within 3 minutes of standing. Recently there has been a lot of discussion about the adequacy of the consensus definition, while it is based on expert opinion and intermittent sphygmomanometric blood pressure measurements. With the increasing use of the noninvasive continuous blood pressure measurement (Nexfin) there is a better understanding of the different orthostatic blood pressure recovery patterns. However, there is no clear definition for these different orthostatic blood pressure recovery patterns. The orthostatic blood pressure recovery patterns that have been described, can be divided into *normal recovery*, *slow recovery*, *no recovery*, *initial orthostatic hypotension*, *delayed orthostatic hypotension* and *reflex syncope*.

Syncope is 1-2% of the reasons for referral to the emergency department (ED) whereby in up to 28% OH is listed as the cause. Measurement of the orthostatic blood pressure is, according to the syncope guideline, part of the initial evaluation of syncope in the ED. There are different ways to measure orthostatic blood pressure changes. In the daily practice, the active

lying-to-standing test is the most suitable test, as it corresponds with real life situations, is simple to perform and requires minimal patient cooperation. Next to the call for revision of the consensus definition, a more standardized and precise orthostatic blood pressure measurement method is recommended to be implemented in the guidelines. The orthostatic blood pressure measurement with sphygmanometer is too imprecise, too infrequently repeated during standing and there is a wide variation in the measurement procedures and interpretation to measure orthostatic hypotension in a sufficiently reliable matter. Orthostatic blood pressure measurement with Nexfin seems to be very suitable. It can identify orthostatic hypotension, as well as different blood pressure recovery patterns including initial orthostatic hypotension, a clinically unrecognized cause of syncope.
The clinical relevance of these different blood pressure recovery patterns still needs to be identified before it can be used as a standard diagnostic tool in the ED.
Next to the orthostatic blood pressure recovery patterns, different types of pathophysiological changes have been recognized in orthostatic hypotension, respectively arteriolar, venous and mixed. In the arteriolar type it is mainly an impaired vasocontrictive mechanism to stress, in the venous type there is an excessive decrease in venous return that is reflected in a sharp fall in the cardiac output and in the mixed type there is a combination of both. When taking the orthostatic blood pressure recovery patterns and the pathophysiological types into account, it is possible to come to a rational treatment. There have been many studies describing the different orthostatic blood pressure recovery patterns and linking them to symptoms and mortality, but no intervention and follow up of these patterns has been done.
Investigation of orthostatic blood pressure changes is primarily done in the ED in the evaluation of syncope patients. The evaluation of syncope patients in the ED is challenging, because most patients are asymptomatic at the arrival to the ED. The aim of the evaluation is to detect the mechanism and the cause of syncope, to be able to give the patient an effective, preventive treatment and to determine the direct and long-term prognostic risk. The European Society of Cardiology (ESC) has issued a syncope guideline to achieve a more efficient initial evaluation. According to the ESC guideline the initial evaluation of syncope consists of careful history and physical examination, including orthostatic blood pressure measurement and electrocardiogram. Without any further investigations the attending physician can make a diagnoses based on the initial evaluation in 50- 63% of the syncope patients. In 21% of the syncope patients the diagnosis could be made after the initial evaluation combined with an additional history by a syncope expert. The additional value of Nexfin in the initial evaluation and work-up of the syncope patient in the ED still needs to be investigated. We hypothesize that following the ESC guidelines with the initial evaluation together with Nexfin orthostatic measurement and careful history taking more (correct) diagnosis will be made. We also hypothesize that in (pre-) syncope patients with an abnormal blood pressure recovery pattern an improvement of the abnormal blood pressure recovery pattern with a directed treatment will give a reduction of (pre-)

syncope recurrence and improvement in quality of life. In patients with (pre-) syncope with a normal blood pressure recovery pattern we expect a reduction of (pre-) syncope and an improvement in quality of life due to (non-) medical advices and treatment. We expect that Nexfin will be of prognostic added value in both the initial evaluation as the follow-up period. At the end of this study we hope to develop a more standardized orthostatic blood pressure measurement method that can be used in the ED.

Study objective

The main objective of the study is to determine the diagnostic and prognostic added value of careful history taking and 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 and quality of life.

Study design

The study is a prospective, single-center intervention study. The estimated duration of the study is 2 years. The study will take place in the ED of the university medical center Groningen(UMCG) and will include patients who are referred to the ED due to pre-syncope and syncope. The one-year follow up will take place at the syncope outpatient department, which is part of the internal medicine outpatient department. There will be a randomization 1:1 in the ED between patients who will get an additional Nexfin measurement and patients without this additional measurement. The randomization is done to be able to determine the additional diagnostic and prognostic value of Nexfin in the ED en during follow-up. We chose the intention-to-treat approach, as we are not applying a new treatment and it would be unethical to spare patients from proven care.

Intervention

The study consists of two phases. The first phase is the initial evaluation in the ED, the second phase is the follow-up in the outpatient department. The initial evaluation will be done twice, first by the attending physician and then by the investigator. The follow-up at the outpatient department will be part of standard care. Patients will be asked to fill in a quality of life questionnaire (SF-12) at the beginning and end of the follow-up period. They will also be asked to do a MMSE and fill in the Barthel Index at their first outpatient department visit. Next to this they will be requested to keep up a diary about their (pre-)syncope complaints during the follow-up year.

Study burden and risks

Orthostatic blood pressure measurement is part of the initial evaluation of (pre-)syncope patients in the ED.The burden for the patient in the ED is the additional history taking and physical examination. The follow-up investigations and treatment at the syncope outpatient department are part of standard care. The burden for the patient is the request to keep up a diary about their (pre-) syncope complaints during one year, a quality of life questionnaire (SF-12) will be taken at the beginning and end of the study and once a MMSE and Barthel index will be performed (in patients of 60 years and older). The patients receive standard care, but because they are participating in a study, they are asked to have regular outpatient department visits during 1 year. This means that some patients have more outpatient department visits than they would normally require.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

• The patient must be 18 years or older.
• The reason for referral to the emergency department must be (pre-) syncope.
• The patient must be able to stand for 5 minutes with little assistance.

Exclusion criteria

• The patient is not able to stand for 5 minutes (with little assistance)
• 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 has a MMSE score <21 during the first outpatient clinic visit
• The patient is geographically or otherwise inaccessible to follow up
• The patient is unwilling or unable to give informed consent
• The patient has atrial fibrillation in the emergency department
• 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
• If Nexfin measurement is not possible, for example due to deformation of the fingers, Raynaud's phenomenon or peripheral vasoconstriction

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	01-12-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	09-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 29397
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL53080.042.15
OMON	NL-OMON29397