DEVELOPING A DIAGNOSTIC PROTOCOL FOR DIZZY ELDERLY PATIENTS IN PRIMARY CARE

Published: 03-07-2006
Last updated: 14-05-2024

To construct an optimal diagnostic protocol enabling general practitioners to distinguish between dizzy elderly patients who need treatment, dizzy elderly patients who need further diagnostics and dizzy elderly patients who need no further…

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON30081

Source
ToetsingOnline

Brief title
DIEP

Condition

- Cardiac arrhythmias
- Middle ear disorders (excl congenital)
- Peripheral neuropathies

Synonym
dizziness, presyncope

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Intervention

Keyword: diagnostics, dizziness, elderly, etiology

Outcome measures

Primary outcome

The combination of tests that is most discriminative in dizzy elderly patients

with the judgement of an expert panel on the most desired medical management as

reference. We aim to formulate diagnostic (prognostic) rules for the management

of dizziness in elderly in general practice.

De combinatie van testen die het meest onderscheidend is bij duizeligheid van

de oudere patiënt ten opzichte van de referentiestandaard: het oordeel van een

deskundigenpanel ten aanzien van het te voeren beleid. Het streven is om

diagnostische (en prognostische) regels te formuleren ten aanzien van het

beleid bij duizeligheid bij ouderen in de huisartspraktijk.

Secondary outcome

In the study for determinants the endpoints are clinical profiles, i.e.

combinations of conditions (physical and/or mental), known by certain test

results, that correlate with the complaint of dizziness. With a panel diagnosis

as reference standard we will be able to determine the diagnostic odds ratio

and likelihood ratios of diagnostic tests or combination of tests for some

frequently occurring diagnoses.

- diagnostic profiles, i.e. combinations of conditions (physical and/or

mental), that correlate with the existance of complaints of dizziness.

-diagnostic odds ratios and likelihoodratios of (combinations of) test results

for some highly prevalent diagnsoses.

Study description

Background summary

Much is unknown about the cause and prognosis of dizziness (especially in the elderly) and the benefit of further diagnostics. An integrated and multivariate approach to quantify which conditions contribute to the complaints of dizziness and which diagnostic tests contribute to the diagnostic process and management of dizziness in the elderly is needed

Study objective

To construct an optimal diagnostic protocol enabling general practitioners to distinguish between dizzy elderly patients who need treatment, dizzy elderly patients who need further diagnostics and dizzy elderly patients who need no further diagnostics and for whom a wait & see policy is recommended. Other objectives of this study are to obtain a better understanding of determinants contributing to dizziness in the elderly and to assess the test characteristics of the tests used to diagnose dizziness in the elderly.

Study design

In patients presenting with complaints of dizziness and in a matched group of non-dizzy patients a standardised diagnostic testprotocol will be applied. This protocol consists of 22 tests, which were considered by an international expertpanel as possibly contributory to diagnosing dizziness in the elderly and feasible in primary care.
The study exists of three parts: an evaluation of the diagnostic protocol with emphasis on prognosis in a cross-sectional design; the determination of determinants to dizziness in the elderly in a case control design; an evaluation of test characteristics of used tests with emphasis on diagnosis in a cross-sectional design. The results of diagnostic tests are the independent variables. Three different dependant variables are used: 1. the judgement of a panel of experts on medical management 2. the presence oo dizziness 3. the diagnosis, as given by the expert panel.

Study burden and risks

The risks for patients and controls participating in this project will be negligible. We apply no medical therapeutic interventions, other than usual care. There will be some burden for patients and controls, due to their age, probable impairments and complaints. Performance of the protocol takes about 45 minutes and a capillary puncture is required to measure hemoglobin and glucose. If possible we perform tests in sitting or lying position. There are no direct benefits for controls. The benefit for patients is the identification of contributing factors to their dizziness. With this knowledge their GP*s can at least inform them, and sometimes guide them in treatment and appropriate specialist referral, if required.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

consultation in general practice for dizziness

Exclusion criteria

- no complaints of dizziness at inclusion (which will be about 3-4 weeks after peresentation to the general practitioner)
- not able to communicate in Dutch or English
- cognitive impairment
- blindness (visual acuity < 3/60 in the better seeing eye. This means that the better seeing eye cannot identify the orientation of the break in the top ring at three metres on the Landolt*s broken-ring chart)
- deafness (permanent and profound loss of hearing in both ears with more than 90 decibels loss on the three frequencies of the Fletcher -index)
- totally wheelchair bound

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2006
Enrollment:	620
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL11947.018.06