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A study to improve the diagnosis of vertigo in general practice

Submission date
14/02/2023

Recruitment status
Recruiting

Registration date
16/02/2023

Overall study status
Ongoing

Last Edited
04/04/2024

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Vertigo is a common symptom that increases with age. The impact for patients is enormous: four out of five patients with vertigo report severely impairing symptoms, leading to sick leave, medical consultation, interruption of daily activities, and/or avoidance of leaving the house. In older patients, vertigo is associated with anxiety, depression, social isolation, and falling. The economic burden is substantial, due to repeated consultations, excessive use of diagnostic imaging, emergency care, and decreased productivity.
More than 80% of the patients with vertigo are primarily treated by their general practitioner (GP) and never referred to a medical specialist. Despite this therapeutic responsibility, the GP's diagnostic toolkit has serious limitations. All recommended tests lack empirical evidence because a diagnostic accuracy study on vestibular disease has never been performed in primary care. This scientific gap was identified and highly prioritized by the National General Practice Research Agenda (4.5.6 NERVOUS SYSTEM, ICPC N; priority 3/10; ID 549/554). The VERtigo DIagnosis study (VERDI, a famous Italian composer who experienced frequent episodes of dizziness and died of stroke) will fill this gap. The researchers will construct a diagnostic algorithm that enables GPs to identify more accurately and efficiently underlying causes in patients with vertigo. This may lead to faster and more targeted treatment, less diagnostic imaging and referral, less prescribing of antivertigo drugs, and improvement of the overall outcome for patients with vertigo in general practice.
The main aim of this study is to investigate the diagnostic accuracy of history taking and physical examination for patients with vertigo in general practice, in order to construct an easy-to-use diagnostic algorithm for daily clinical practice.
The key objectives are:
1. To assess the existing evidence on the accuracy of tests for diagnosing causes of vertigo in general practice
2. To determine which tests should be investigated in a diagnostic accuracy study for patients with vertigo in general practice
3. To investigate the diagnostic accuracy of selected tests for patients with vertigo in general practice
4. To construct an easy-to-use diagnostic algorithm for vertigo in general practice
5. To compare the diagnostic accuracy of GP judgement with the constructed diagnostic algorithm

Who can participate?
Patients aged 18 years and over with a new episode of vertigo presenting in general practice

What does the study involve?
Patients will undergo a battery of diagnostic tests during a home visit.

What are the possible benefits and risks of participating?
With the results of the proposed study patients will faster and more frequently receive an appropriate diagnosis, leading to more adequate treatment and thus potentially improving the outcome of their symptoms.
With the constructed diagnostic algorithm, GPs will be able to more accurately and efficiently identify underlying causes in patients with vertigo. This may lead to faster treatment, more targeted treatment, less use of diagnostic imaging, less referral to secondary/tertiary care, and an improvement of the overall outcome for patients with vertigo in general practice.
With faster and more accurate diagnoses, patients can often be treated in general practice and expensive additional testing and referral to secondary/tertiary care can be avoided.
The risks of participating in the VERDI study were assessed as 'negligible', which was approved by the Medical Ethics Committee of the Amsterdam UMC.

Where is the study run from?
Amsterdam UMC, location VUmc (Netherlands)

When is the study starting and how long is it expected to run for?
January 2021 to December 2027

Who is funding the study?
ZonMw (Netherlands)

Who is the main contact?
Dr O.R. Maarsingh, o.maarsingh@amsterdamumc.nl

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ZonMw 10060022010003

Study information

Scientific Title
The diagnostic accuracy of history taking and physical examination for patients with vertigo in general practice: the VERDI study

Acronym
VERDI

Study objectives
Background
Vertigo is a common symptom that increases with age. The impact for patients is enormous: four out of five patients with vertigo report severely impairing symptoms, leading to sick leave, medical consultation, interruption of daily activities, and/or avoidance of leaving the house. In older patients, vertigo is associated with anxiety, depression, social isolation, and falling. The economic burden is substantial, due to repeated consultations, excessive use of diagnostic imaging, emergency care, and decreased productivity.
More than 80% of the patients with vertigo are primarily treated by their general practitioner (GP) and never referred to a medical specialist. Despite this therapeutic responsibility, the GP's diagnostic toolkit has serious limitations. All recommended tests lack empirical evidence, because a diagnostic accuracy study on vestibular disease has never been performed in primary care. This scientific gap was identified and highly prioritized by the National General Practice Research Agenda (4.5.6 NERVOUS SYSTEM, ICPC N; priority 3/10; ID 549/554). The VERtigo DIagnosis study (VERDI, a famous Italian composer who experienced frequent episodes of dizziness and died of stroke) will fill this gap. The researchers will construct a diagnostic algorithm that enables GPs to identify more accurately and efficiently underlying causes in patients with vertigo. This may lead to faster and more targeted treatment, less diagnostic imaging and referral, less prescribing of antivertigo drugs, and improvement of the overall outcome for patients with vertigo in general practice.

Main objective
To investigate the diagnostic accuracy of history taking and physical examination for patients with vertigo in general practice, in order to construct an easy-to-use diagnostic algorithm for daily clinical practice.

Key objectives
1. To assess the existing evidence on the accuracy of tests for diagnosing causes of vertigo in

general practice
2. To determine which tests should be investigated in a diagnostic accuracy study for patients with vertigo in general practice
3. To investigate the diagnostic accuracy of selected tests for patients with vertigo in general practice
4. To construct an easy-to-use diagnostic algorithm for vertigo in general practice
5. To compare the diagnostic accuracy of GP judgement with the constructed diagnostic algorithm

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/02/2023, the Medical Ethics Committee of Amsterdam UMC (Medical Ethics Review Committee Amsterdam UMC, Boelelaan 1117, 1081 HV, Amsterdam, the Netherlands; Tel: not available; Email: not available), ref: NL83111.029.22

Study design
Observational diagnostic accuracy study

Primary study design
Observational

Secondary study design
Diagnostic accuracy study

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients with a new episode of vertigo and/or episodic vestibular syndrome in general practice

Interventions
First, the researchers will perform a systematic review (I) to assess the empirical evidence on diagnostic tests for patients with vertigo in general practice. The most promising tests will be studied during an international Delphi procedure (II) to determine which tests should be investigated in a diagnostic accuracy study (III). During this study, the researchers will compare each index test with its respective reference standard. They will focus on five target conditions that account for more than 95% of vertigo diagnoses in general practice: 1. benign paroxysmal positional vertigo (BPPV), 2. vestibular neuritis, 3. Meniere’s disease, 4. vestibular migraine, and 5. central causes of vertigo. As these five target conditions have a different pathophysiology and all lack a generally accepted reference standard, the researchers will use consensus diagnosis as the reference standard. Data for each patient, including history, physical examination, and additional tests as recommended by international guidelines, will be recorded on a standardized

form and independently reviewed by a neurologist and otorhinolaryngologist. For each patient, the reviewers have to decide about the presence/absence of each target condition. The researchers will calculate sensitivity, specificity, predictive values, and likelihood ratios, followed by decision rules for each target condition. Subsequently, they will conduct semi-structured interviews among patients and GPs to investigate barriers and facilitators for the successful implementation of the decision rules. The results of the interviews will be used to construct a final overarching diagnostic algorithm (IV). As clinical decision rules may have a limited effect on physicians, the researchers will perform a comparison study (V) to compare the accuracy of GP judgement with the constructed diagnostic algorithm.

Intervention Type
Other

Primary outcome measure
Diagnostic accuracy is measured using sensitivity, specificity, positive and negative predictive values, positive and negative likelihood ratios, and diagnostic odds ratios at a single timepoint

Secondary outcome measures
The methodological quality of diagnostic accuracy studies, measured using the revised Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) checklist at a single timepoint

Overall study start date
01/01/2021

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. New episode of vertigo and/or episodic vestibular syndrome (definition: see below)
3. Presentation of symptoms during (telephone) consultation or home visit

Definition of vertigo:
The VERDI study will adopt the nomenclature of the Bárány society, the leading international organization for clinicians and researchers involved in vestibular medicine. The Bárány society previously realized the International Classification of Vestibular Disorders (ICVD), a uniform way to describe vestibular symptoms. The VERDI study will focus on patients with vertigo (defined by the ICVD as “the sensation of self-motion when no self-motion is occurring or the sensation of distorted self-motion during an otherwise normal head movement”) and/or episodic vestibular syndrome (defined by the ICVD as “clinical syndrome of transient vertigo, dizziness, or unsteadiness lasting seconds to hours, occasionally days, and generally including features suggestive of temporary, short-lived vestibular system dysfunction”). When assessing a patient with vestibular symptoms, the Bárány society recommends focusing on timing (onset, duration, and evolution of symptom) and triggers (actions, movements, or situations that provoke the onset of symptoms. During the diagnostic accuracy study, the researchers will investigate the diagnostic value of timing, triggers, and other (individual and combinations of) items of history taking.

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Calculated sample sizes per target condition BPPD: n=403; vestibular neuritis: n=110; Ménière's disease: n=189; central causes: n=960; vestibular migraine: n=? (necessary data on disease prevalence in primary care are lacking). In order to have sufficient power for all target conditions, the aim is to include 960 participants.

Key exclusion criteria
1. Serious comorbid conditions that preclude participation in the VERDI study (judgement of patient's GP)
2. Severe cognitive impairment (judgement of patient's GP)
3. Insufficient mastery of Dutch and English language

Date of first enrolment
01/03/2023

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC, location VUmc
Boelelaan 1117
Amsterdam
Netherlands
1081HV

Sponsor information

Organisation
Amsterdam UMC Location VUmc

Sponsor details
Boelelaan 1118
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Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
The results of research will be submitted for publication to peer-reviewed scientific journals. Publication will be in accordance with the basic principles of Central Committee on Research Involving Human Subjects (CCMO) statement on publication policy.

Intention to publish date

01/03/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Otto R. Maarsingh (o.maarsingh@amsterdamumc.nl).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/04/2024	04/04/2024	Yes	No