Providing diagnostic accuracy in acute onset, continuous dizziness.

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To determine the sensitivity and specificity of the HINTS+ test in detecting a central cause in patients with acute onset, continuous dizziness in a general ED population, when performed by general neurologists/ED physicians.

Ethical review	Approved WMO
Status	Completed
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational invasive

Summary

ID

NL-OMON52153

Source
ToetsingOnline

Brief title
PROVIDE

Condition

- Inner ear and VIIIth cranial nerve disorders
- Central nervous system vascular disorders

Synonym
cerebral infarction. Acute Vestibular Syndrome., Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: ZonMw (ZE&GG),Neurobit Technologies,Sint Jacobusstichting. In-kind contribution Neurobit Technologies.

Intervention

Keyword: Acute Vestibular Syndrome, Dizziness, HINTS+, Vertebrobasilar stroke

Outcome measures

Primary outcome

Primary endpoint is final diagnosis by the expert panel after three months.

Secondary outcome

Secondary endpoints are health care costs, sensitivity/specificity of early

(<24-48 hours) and delayed (>72 hours and <10 days) MRI of the brain and of a

biomarker.

Study description

Background summary

Acute onset, continuous dizziness (AOCD, previously also known as isolated vertigo) without focal neurological deficits is one of the most challenging symptoms in the emergency department (ED). Most patients with these complaints will have a benign disorder of the vestibular system. However, some patients will suffer from a central problem, mostly stroke. The challenge in differentiating between these diagnoses lies in the identical presentation. AOCD is a very common symptom at the ED. It is assumed to represent 3% of all ED visits in the United states. To emphasize the difficulty we have in determining the correct diagnosis, approximately 130.000-200.000 strokes in all these patients are missed each year. Conventional neurologic examination is notoriously unreliable and CT imaging has a poor specificity and sensitivity. MRI of the brain is thought to be the gold standard, even though 12% of posterior circulation strokes could be missed if MRI is performed within 48 hours. This may even rise up to 23% if MRI is performed within 24 hours. The HINTS+ test (Head Impulse, Nystagmus, Test of Skew and Hearing Loss) has been proposed as a bedside test with an excellent sensitivity and specificity of around 100% and 90% respectively to discriminate between a central and peripheral cause. However, most of the studies regarding the HINTS+ test are small sized and are performed in a small number of specialized tertiary neuro-otology centers with highly selected patients. The external validation has yet to be performed. Further research with more inclusive selection paradigms is needed to validate the accuracy of the HINTS+ test and MRI in

AOCD. Moreover, other diagnostic tests should be taken into account (e.g. video assisted HINTS+ test and biomarker investigation) to further improve diagnostic accuracy in this patient population.

Study objective

To determine the sensitivity and specificity of the HINTS+ test in detecting a central cause in patients with acute onset, continuous dizziness in a general ED population, when performed by general neurologists/ED physicians.

Study design

A prospective multi-center cohort investigation.

Study burden and risks

The burden of this study is an extra questionnaire and a single venous puncture. In a selected group of patients an extra MRI scan will be performed (one group with gadolinium contrast and one group without gadolinium contrast).

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

- Acute onset, continuous dizziness, still present at arrival on the ED as the principal reason for the ED visit.
- Presentation within 24 hours after onset of dizziness.
- Age 18 years or older.
- For substudy 1: Presentation at the ED of one of the following centers: Haaglanden Medical Center, Haga Hospital, Jeroen Bosch Hospital or Gelre Hospital.
- For substudy 1: Early MRI DWI <48 hours of symptom onset without explanatory lesion.
- For substudy 2: Presentation at the ED of the Haga Hospital.
- For substudy 2: Vestibular neuritis as most probable diagnosis as determined by the treating physician on the ED, based on i.a. horizontal-torsional nystagmus in one direction and positive HIT.

Exclusion criteria

- Clear signs of benign paroxysmal positional vertigo (BPPV) (i.e. acute onset, continuous dizziness successfully treated by canalith repositioning).
- Recognizable recurrent vertigo or acute onset dizziness compatible with a known previous diagnosis of Meniere*s disease or vestibular migraine;
- New deficits upon neurological examination (i.e. ataxia, dysarthria, spontaneous skew deviation, gaze palsy or lowered state of consciousness (i.e. Glasgow Coma Scale (GCS) score <14)). Nystagmus and gait imbalance are allowed.
- Known pregnancy at the time of inclusion.
- Known contra-indication for MRI (e.g. claustrophobia, non MRI-compatible pacemaker or ICD).
- Clear medical condition other than a central or a peripheral vestibular disorder that explains acute onset, continuous dizziness. Examples are hypotension, sepsis, medication related.
- Previous inclusion in this study.
- Unable to undergo follow up (e.g. life expectancy <3 months, severe cognitive impairment, no permanent residence in the Netherlands).
- Unable to give informed consent (e.g. cognitive impairment, mental retardation).
- Insufficient command of the Dutch language.

- For substudy 2 additional exclusion criterium: known allergy to gadolinium.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-08-2021
Enrollment:	800
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	06-05-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	09-08-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL76143.058.21
Other	NL9197