Providing diagnostic accuracy in acute onset, continuous dizziness.

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We hypothesize that the HINTS+ test is more reliable than early MRI imaging in patients with acute onset continuous dizziness. As a result it is hypothesized that HINTS+ clinical examination leads to lower costs and an improvement in Quality of Life.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21345

Bron
Nationaal Trial Register

Verkorte titel
PROVIDE

Aandoening

Acute vestibular syndrome. Vertebrobasilar/cerebellar stroke. Peripheral vestibular syndrome.

Ondersteuning

Primaire sponsor: Haaglanden Medical Center
Overige ondersteuning: ZonMw Grant "Zorg Evaluatie & Gepast Gebruik (ZE&GG) - extra ronde 2019" (ZonMw Grant number 10330022010010).
Co-financing St. Jacobusstichting.
In-kind contribution Neurobit Technologies.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Final diagnosis (stroke or peripheral) 3 months after inclusion.

Toelichting onderzoek

Achtergrond van het onderzoek

This study is a prospective, multicenter, cohort investigation to determine the optimal diagnostic work-up for patients with isolated, acute onset, continuous dizziness presenting to emergency departments. Patients 18 years and older presenting to the ED with acute onset, continuous dizziness and without neurological deficits or clear other diagnosis will be included in this study. All patients will undergo HINTS+ test, standarized questionnaires and MRI brain within 24 hours A selected group of patients will undergo a MRI brain after 72 hours as well. Follow-up time is 3 months, with the primary study parameter being ‘final’ diagnosis after 3 months. We will determine the sensitivity, specificity, positive predictive and negative predictive value of both the HINTS+ test as MRI brain within 24 and after 72 hours. Furthermore we will perform an economic evaluation of the HINTS+ test using a budget impact analysis and cost utility analysis. Eventually study data will be used to draft a national guideline and decision model for the diagnostics and treatment of isolated, acute onset, continuous dizziness.

Doel van het onderzoek

We hypothesize that the HINTS+ test is more reliable than early MRI imaging in patients with acute onset continuous dizziness.
As a result it is hypothesized that HINTS+ clinical examination leads to lower costs and an improvement in Quality of Life.

Onderzoeksopzet

Day 0, Day 1, Day 3, Discharge, Follow-up after 3 months.

Onderzoeksproduct en/of interventie

Not applicable.

Contactpersonen

Publiek

Haaglanden Medisch Centrum
Merel Verhagen

088-9797900

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Acute onset, continuous dizziness, still present at arrival on the ED;
- Presentation within 24 hours after onset of dizziness;
- Age 18 years or older.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Clear signs of benign paroxysmal positional vertigo (BPPV) (i.e. acute onset, continuous dizziness successfully treated by canalith repositioning);
- A history of recognizable recurrent vertigo or acute onset, continuous dizziness compatible with Meniere’s disease or vestibular migraine;
- Deficits upon neurological examination other than a nystagmus (i.e. ataxia (gait imbalance is allowed), dysarthria, spontaneous skew deviation, gaze palsy or lowered state of consciousness (i.e. EMV <14));
- Pregnancy at the time of inclusion;
- Known contra-indication for MRI (e.g. claustrofobia, non MRI-compatible pacemaker or ICD);
- Clear medical condition other than stroke (central) or non-stroke (peripheral) vestibular disorder that explains acute onset, continuous dizziness. Examples are hypotension, sepsis, medication related;
- Previous inclusion in study;
- No informed consent;
- Unable to undergo follow up (e.g. life expectancy <3 months, severe cognitive impairment, no permanent residence in the Netherlands);

- Insufficient command of the Dutch language.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2021
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9197
Ander register	METC LDD (Leiden Den Haag Delft) : P21.029 METC LDD

Resultaten