Point-of-care ultrasound of optic nerve sheath diameter in suspected hypertensive emergency*

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The aim of this study is to assess if ultrasonography of the ONSD can be used to safely rule out papilledema and to evaluate if ONSD measurement can replace funduscopy in the assessment of certain patients with suspected hypertensive emergency.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56796

Source
ToetsingOnline

Brief title
OpticUS

Condition

- Central nervous system vascular disorders
- Vascular hypertensive disorders

Synonym
swelling of the optic disc, very high bloodpressure

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hypertensive emergency, Nervus opticus, Point-of-care ultrasound

Outcome measures

Primary outcome

The negative predictive value of ultrasonography of the ONSD for the diagnosis papilledema (grade 4 hypertensive retinopathy).

Secondary outcome

- Diagnostic characteristics of the ultrasonographic presence of bulging of the optic nerve head, crescent sign and/or decrease of ONSD with lateral eye movement for the diagnosis of papilledema.
- Diagnostic characteristics of ultrasonography of the ONSD for the diagnosis of hypertensive encephalopathy
- Diagnostic characteristics of ultrasonography of the ONSD for the need of intravenously administered rapid blood lowering medications
- To evaluate the role of the ONSD measurement in the assessment of patients with suspected hypertensive emergency
- The agreement between funduscopy findings and non-mydriatic ocular fundus photography findings

Study description

Background summary

Hypertensive emergencies are acute, life-threatening conditions resulting from markedly increased blood pressure, characterized by acute, ongoing target-organ damage. They require fast diagnosis and management. Organ damage includes hypertensive retinopathy grade 3 and/or 4, which is associated with other acute

hypertension-mediated organ damage. Clinical assessment of patients presenting with possible hypertensive emergency includes therefore imaging of both fundi, typically fundoscopy by an ophthalmologist in the case of vision loss/symptoms or if no other apparent organ damage is present that already requires rapid blood pressure lowering medication.

Measurement of the optic nerve sheath diameter (ONSD) by point-of-care ultrasonography (POCUS) is performed by internal medicine doctors to support the evaluation of above-mentioned patients. Measurement of ONSD is based on the fact that the subarachnoid space around the optic nerve is in continuity with the intracranial subarachnoid space. (5) Hence, any raised ICP will be transmitted to the optic nerve subarachnoid space. From earlier studies we know that ONSD correlates with elevated ICP in patients with suspected intracranial hypertension. The cut-off value of the ONSD to diagnose an ICP > 20mmgHg varies in literature between 4.80 and 5.86. Furthermore, ONSD correlates well with different stages of papilledema in a case-control study of patients with papilledema, and changes in ONSD are noticeable even in very early papilledema. Hypertensive retinopathy consists of focal and diffuse arteriolar narrowing, with retinal hemorrhage (grade 3), and papilledema (grade 4). In the context of patients presenting with hypertension Roque et al. found a significant correlation with systolic and diastolic blood pressure, however they did not investigate the correlation of ONSD with clinical endpoints that have therapeutic consequences, like hypertensive retinopathy or hypertensive encephalopathy that require immediate and fast decrease in blood pressure. The diagnostic characteristics of the ONSD in the context of patients presenting with a suspected hypertensive emergency are unknown.

Study objective

The aim of this study is to assess if ultrasonography of the ONSD can be used to safely rule out papilledema and to evaluate if ONSD measurement can replace funduscopy in the assessment of certain patients with suspected hypertensive emergency.

Study design

This is a prospective observational multi-centre clinical study.

Study burden and risks

There is a minimal burden The ultrasound of the optic nerve is already standard care in some centers. This examination is non-invasive, non-damaging and takes a few minutes. This is performed during the patient's emergency room visit. This visit will not be prolonged because of the ultrasound examination.
The fundus examination, which is not covered by regular care in only a small number of patients, has very minimal risks, since eye drops (mydriatics) are

given. This is only done for patients who are already admitted to hospital, the length of their stay will not be extended.

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

>= 18 years old
suspected hypertensive emergency

Exclusion criteria

- Patients with preexisting optic nerve head changes such as glaucoma,

pre-existing retinal artery/vein occlusions or any other condition that makes assessment of the fundi impossible.
- Primary neurological cause of hypertension: ischemic cerebrovascular incident

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2024
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	03-06-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	07-11-2024
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	NL84914.058.23