Microvascular dysfunction in malignant hypertension; evaluation of the endothelial glycocalyx.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular hypertensive disorders
Study type	Observational invasive

Summary

ID

NL-OMON32232

Source
ToetsingOnline

Brief title
Mistletoe

Condition

- Vascular hypertensive disorders

Synonym
hypertensive crisis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cerebral oxygenation, endothelium, glycocalyx., malignant hypertension, microvascular function

Outcome measures

Primary outcome

Microvascular glycocalyx volume changes

Secondary outcome

Coagulation activation

Endothelial activation

Glycocalyx degradation products

Oxidative stress measurements

Study description

Background summary

Patients with a hypertensive crisis are at high risk of developing accelerated target organ damage, but the mechanisms by which these extreme blood pressure elevations are translated into acute vascular target organ injury have not been defined. We previously showed that cerebral autoregulation is impaired in patients with severe hypertension and retinal lesions (i.e. malignant hypertension). It remains unclear however whether reductions in cerebral blood flow are also associated with decreased delivery of oxygen to the cerebrovascular bed and whether this is different for patients having malignant hypertension and patients with severe hypertension who lack retinal abnormalities. In the present study we will examine differences in microcirculatory glycocalyx in the tongue and oxygen content of the cerebrovascular bed between patients with malignant hypertension and patients with severe hypertension.

Study objective

In the current study we want to evaluate the microcirculatory glyccalyx in patients presenting with malignant hypertension and relate this to patients with severe hypertension. Microcirculation is assessed using SDF imaging,

oxygen supply using NIRS and autoregulation of bloodflow by TCD. Long term changes in the microvasculature and endothelial activation are assessed at the outpatient clinic, after a week and after three months.

Study design

All patients admitted to the ER with a diastolic blood pressure >120 mmHg will be transferred to the Medium Care Unit were they will be treated according to protocol. Before starting infusion of parenteral medication the microcirculation of the tongue will be assessed by SDF imaging, and additional blood (40 ml) will be drawn. After transport to the Medium Care Unit (MCU) for appropriate care, the intravenous infusion of labetolol is started (normal protocol). According to protocol bloodpressure will be lowered with 25% and after 1-, 2- and 4 hours SDF imaging will be performed and blood will be drawn (total max 160ml). Patients are asked to visit the outpatient clinic within a week and after 3 months for standard follow up. During these visits we will evaluate end-organ damage and draw blood for *followup* measurements.

Study burden and risks

Since patients are being teated according to national guidelines and besides extra blooddrwaings are subject to non-invasive measurements, the risk of participation is low. The delay of treatment (<1hr) is within the time-limit set in National guidelines (NIV richtlijn april 2003).

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

Age between 18 and 99 years
Blood pressure above 120 mmHg diastolic on repeated examination
Admission for parenteral bloodpressure lowering treatment with labetalol

Exclusion criteria

Current pregnancy
Intoxications (e.g. cocaine, XTC)
Hypertensive crises treated with other oral or parenteral drugs than labetalol
Contra-indication for beta or alpha blockers.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	40

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	NL23821.018.08