Early Target Organ Damage in patients with Hypertension: a Magnetic Resonance Imaging (MRI) Approach

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To assess early hypertensive induced target organ damage using Magnetic Resonance Imaging (MRI) technology. To relate microalbuminuria and low grade systemic inflammation to cardiac, cerebral and aortic target organ damage. Emphasis will be on young…

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON31305

Source
ToetsingOnline

Brief title
MRI-assesment of target organ damage in hypertension

Condition

- Heart failures
- Central nervous system vascular disorders
- Vascular hypertensive disorders

Synonym
high blood pressure, Hypertension

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: Hypertension, MRI (3T), Target Organ Damage (TOF)

Outcome measures

Primary outcome

Manifestations of early end organ damage in patients with hypertension (i.e.

the underneath mentioned MRI outcomes will be used to compare these between

earlier mentioned hypertension subgroups):

Heart:

- Left Ventricular Function, Ejection Fraction, Volume and Mass

- Delayed Contast Enhancement (DCE) to extent transmural left ventricular scar

tissue

Aorta:

- Aortic wall compliance by distensibility and Pulse-wave velocity (PWV)

Brain:

- Precense and size of white matter lesions;

- Presence and size of lacunar and cortical infarctions;

- Brain atrophy and gray/white matter volumes;

- Integrity of white matter fibers;

- Prevalence of microbleeds.

Secondary outcome

The severity of early cardiac, cerebral and aortic target organ damage as

assessed by 3 Tesla MRI, leading to more appropriate risk stratification for

cardiovascular diseases in patients with hypertension. In our study we will

assess early hypertensive induced target organ damage using Magnetic Resonance Imaging (MRI) technology with special emphasis on young patients and therapy resistant patients. Microalbuminuria and low grade systemic inflammation are expected to adversely affect the severity of target organ damage.

Study description

Background summary

Hypertension causes target organ damage. It results in stroke, heart and renal failure in many but not all patients. Early recognition of patients developing organ damage may result in optimal early treatment in those most likely to suffer from the deleterious consequences of hypertension. Recently, MRI has been established as a more accurate tool for assessment of organ damage in the heart, the aorta and the brain.

Study objective

To assess early hypertensive induced target organ damage using Magnetic Resonance Imaging (MRI) technology. To relate microalbuminuria and low grade systemic inflammation to cardiac, cerebral and aortic target organ damage. Emphasis will be on young patients and patients with therapy resistant hypertension.

Study design

This is a cross-sectional observational study with a case control design. Consenting patients referred to the Leiden University Medical Center (LUMC) hypertension outpatient clinic that fulfill the criteria will have 3 Tesla (T) MRI assessment of brain, heart and aorta. The 3T MRI assessments will be performed using well established techniques currently available at the department of Radiology at the LUMC. Studies will be performed in two to three years.

Study burden and risks

Duration time:
MRI-assessment will take 2 hours in total, of which 90 minutes in the MRI-scanmachine.

No radiation doses in MRI.

Patients with hypertension will get an intravenous contrast medium once, i.e. gadolinium. Only 1% of individuals receiving gadolinium develop contrast allergy.

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 >= 18 years
- Patients with proven hypertension (i.e. blood pressure of > 140/90mmHg on repeated examination according to the criteria of the European Society of Hypertension).

Exclusion criteria

- Routine MRI-contraindications (e.g. instable metal implants, pacemaker/ICD, vascular clips, atrial fibrillation or sustained ventricular tachycardia and claustrophobia).
- Pregnancy
- Renal insufficiency as defined by an MDRD < 30 ml/min/1.73m2
- Gadolinium contrast allergy (no contrast)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-09-2007
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL19265.058.07