Utility of BOLD MRI as diagnostic tool in renal artery stenosis in patients with hypertension and chronic kidney disease

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Is the BOLD MRI able to show the difference in the level of oxygenation as a mesurement of ischemia between a in a healthy kidney (

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON43984

Source
ToetsingOnline

Brief title
BOLD MRI in renal artery stenosis

Condition

- Renal disorders (excl nephropathies)

Synonym
chronic kidney disease, chronic renal failure

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: Afdeling radiologie van ZGT

Intervention

Keyword: BOLD MRI, hypertension, renal artery stenosis

Outcome measures

Primary outcome

the level of oxygenation as a measurement of Ischemia

Secondary outcome

- not applicable

Study description

Background summary

Renal artery stenosis is a common cause of essential hypertension. It is expected that it causes ischemic deviations in the kidney. It's therefor very important to diagnose renal artery stenosis in an early stage, so patients can start early with an intervention. This should prevent severe kidney disease. We want to investigate the utility of the BOLD (Blood oxygen level dependent) MRI in the diagnosis of renal artery stenosis.

Study objective

Is the BOLD MRI able to show the difference in the level of oxygenation as a mesurement of ischemia between a in a healthy kidney (<30% renal artery stenosis) and a kidney with more than 70% artery stenosis?

Study design

Prospective case control study without intervention

Study burden and risks

Patients will visit the hospital once. It conserns a MRI scan, to define the level of oxygenation of the kidney. We do not expect any risks, physically and mentally, for our subjects. The risk for participate in our study is very low, since we comply to the conditions of an MRI scan, compare to the checklist MRI of the department of radiology in our hospital.

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 18-80, 10 subjects without renal artery stenosis and without hypertension, 10 patients with renal artery stenosis >70% and with hypertension. Hypertension is defined as more than 140/90 mmHg with or without medication.

Exclusion criteria

preterminal kidney faillure (GFR<30), pregnancy and the common contra-indications for MRI scan

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	MRI Skyra 3 Tesla
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-12-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	04-06-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	20-08-2015
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	25-08-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL51221.044.14