The agreement between KNN volumetry on 1,5 and 3 Tesla brain MRI.

Published: 05-04-2012
Last updated: 28-04-2024

To asses the agreement of KNN volumetry on 1,5 and 3 Tesla MRI.

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

Summary

ID

NL-OMON35363

Source
ToetsingOnline

Brief title
The agreement between KNN volymetry on 1,5 and 3 Tesla brain MRI

Condition

- Central nervous system vascular disorders

Synonym
Brain volume

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: VIDI Grant G.J. Biessels vanaf 1/1/2012,High Potential Grant G.J. Biessels UMC Utrecht t/m 31/12/2011

Intervention

Keyword: automatic, brain volume, field strength, Volumetry

Outcome measures

Primary outcome

The agreement of KNN volumetry applied on 1,5 and 3 Tesla MRI of the same

subject.

Secondary outcome

n.a.

Study description

Background summary

K-Nearest Neighbour (KNN) volumetry is a highly accurate method for segmenting brain MRI into the compartments gray matter, white matter, cerebrospinal fluid and white matter hyperintensities and measuring the volumes of these compartments. KNN volumetry has been successfully applied to 1,5 Tesla brain MRI in several studies at the UMCU that addressed brain volumes in the context of vascular brain disease and cognitive decline.
At present, research projects increasingly rely on 3 Tesla scans. The main reason for switching to 3 Tesla MRI is the superior signal to noise ratio which has advantages for methods other than brain volumetry. Although field strength should not have a major impact on KNN volumetry, it has not been established yet if volumetric results are similar at different field strengths.
In this study we will asses the level of agreement between KNN volumetry on 1,5 and 3 Tesla MRI. Agreement between KNN volumetry on 1,5 and 3 Tesla MRI would allow us to:
- Link volumetric data from 1,5 Tesla projects to 3 Tesla projects.
- Use volumetric data from existing large 1,5 Tesla cohort studies (such as the SMART-Medea study, >1500 MRI scans) as reference data for current and future 3 Tesla projects.
- Perform multicenter studies using both 1,5 and 3 Tesla MRI scans.

Study objective

To asses the agreement of KNN volumetry on 1,5 and 3 Tesla MRI.

Study design

Cross sectional observational study.

Study burden and risks

The burden associated with participation is that subject will receive two brain MRI scans on the same day. No contrast agent will be administered. Total scan time will be approximately one hour. There are no known risks associated with brain MRI scanning.

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

We will select our subjects from a cohort of patients with Chronic Idiopatic Axonal Perpiheral neuropathy (CIAP).
Inclusion criteria:

Age 50-80 years, a history of cardiovascular disease, 1 or more of the following cardiovascular risk factors: hypertension, diabetes mellitus, BMI > 29, > 10 packyears.

Exclusion criteria

Not living independently. History of brain disease. Contra-indication for MRI: AICD/ICD (automatic heartdefibrillator), Aneurysm clips in the brain placed before 1986 (AZU) or 1990 (Tilburg), Recent endoscopically placed clips in the intestinal system, Breast (mamma) expander with magnets, Cochleair implants, Metal corpus alienum in the eye, Electrical wires (pacemaker wires, ECG wires), Implanted insulin pump, Heart valve prothesis Braunwald - Cutter, Neurostimulator and Vagal Nerve stimulator, Pacemaker, Piston from 1985-1987, Provox ActiValve voisceprothesis, Zenith AAA stent made by Cook, Swan-Ganz catheter, Dental braces, Hydrocefalus pumps, Markers for proton radiation, Piercings, Protheses of 30cm.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	05-04-2012
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL37915.041.11