Ultrasound and Magnetic Resonance Imaging

Published: 02-03-2017
Last updated: 15-04-2024

Radiodiagnostics strongly depends on high image or data quality, well-performed image analyses and information on how pathology appears on the image or data acquired. The objectives of the study are: - In order to improve radiodiagnostic imaging, it...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON54611

Source
ToetsingOnline

Brief title
US and MR imaging

Condition

- Other condition

Synonym
n.a. (multiple conditions)

Health condition

meer dan 3, het betreft onderzoek naar instellingen en toepassingen ten dienste van radiodiagnostiek van meerdere aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,projectfinanciering; dit protocol omvat verschillende projecten,projectfinanciering; dit protocol omvat verschillende projecten

Intervention

Keyword: MRI, MRS, Radiodiagnostics, Ultrasound

Outcome measures

Primary outcome

- Functional and structural Magnetic Resonance Images, i.e. (f)MRI

- Metabolic Magnetic Resonance Spectra (MRS)

- Ultrasound Images (US)

The specific imaging technique will be specified in the project specific

amendment.

Secondary outcome

This study protocol doesn't describe secundary parameters. However, in addition

to the primary study parameters, general parameters characteristics of the

subjects will be collected such as: age, gender, ethnicity and handedness.

Study description

Background summary

The Department of Radiology and Nuclear Medicine (RADNG) conducts basic and applied research in radiodiagnostic imaging, image analysis and in-vivo metabolism. The scientific progress in these fields are driven by the development of complex imaging techniques to obtain structural and metabolic information, and the development of optimal image analysis techniques. Although the department also applies techniques in which ionizing radiation is used, this METC submission is restricted to techniques without ionizing radiation

exposure, i.e. MRI, MRS and US.

Study objective

Radiodiagnostics strongly depends on high image or data quality, well-performed image analyses and information on how pathology appears on the image or data acquired. The objectives of the study are:
- In order to improve radiodiagnostic imaging, it will be investigated if images/data obtained by new or adjusted techniques (software or hardware) have a higher diagnostic quality than those obtained using conventional methods.
- To interpret pathological images, reference images of healthy volunteers will be acquired to define (quantitative) differences between pathology and normal

Study design

Multiple observational explorative studies in humans in two types of studies:
- Image or data acquisition in healthy volunteers or patients
- Extension of a clinical examination of a patient with less than 15 minutes of the normal duration
to test the effect of new techniques (adjusted software or hardware) on image/data quality.

Study burden and risks

The risk associated with participation can be considered negligible- minimal and the burden as minimal. No pharmacological nor (otherwise) invasive or intrusive manipulations will be applied. No direct (health-treatment) benefit is associated with participation.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
NIJMEGEN 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
NIJMEGEN 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Legally competent adults (18 years and older)

Exclusion criteria

- not meeting the inclusion criteria
- with respect to MR projects: MR contra-indication, and claustrophobia

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):	24-04-2017
Enrollment:	800

Type:	Actual

Ethics review

Approved WMO Date:	02-03-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-02-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-06-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-02-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL58944.091.16