Magnetic Resonance Imaging Using Innovative Pulse Sequences

Published: 20-12-2012
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The objective of this study is to acquire a set of images and associated technical information to facilitate regulatory submission of the pulse sequences

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Middle ear disorders (excl congenital)
Study type	Observational invasive

Summary

ID

NL-OMON37074

Source
ToetsingOnline

Brief title
Magnetic Resonance Imaging met behulp van innovatieve pulsreeksen

Condition

- Middle ear disorders (excl congenital)
- Nervous system neoplasms malignant and unspecified NEC
- Cranial nerve disorders (excl neoplasms)

Synonym
Brain disease

Research involving
Human

Sponsors and support

Primary sponsor: GE Healthcare MR Business
Source(s) of monetary or material Support: GE Healthcare

Intervention

Keyword: Brain scan, MRI, Pulse sequences

Outcome measures

Primary outcome

Image quality.

Secondary outcome

NVT

Study description

Background summary

The technology comprising Magnetic Resonance (MR) imaging systems is under continuous development in order to improve the quality of images, speed of acquisition, and usability of MR devices. Collection of in vivo human data plays an important role in enabling the technology to be investigated, optimized, and validated.

Study objective

The objective of this study is to acquire a set of images and associated technical information to facilitate regulatory submission of the pulse sequences

Study design

This is a single-site; open-label, prospective research Study involving patients.

Study burden and risks

With the screening for contraindications, no objective risks are inherent to the use of the MRI and contrast.

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

• Subject must be at least eighteen (18) years of age; and
• Subject must be willing and able to undergo verbal and written informed consent; and
• Subject must have a clinical indication for a head MRI with and without Gadolinium-based contrast agent administration

Exclusion criteria

• Any contraindication to administration of an MRI contrast agent.
• Off-label utilization of contrast agents administered for the subject*s clinical exam.

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):	30-01-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL41921.078.12