Acute neurocognitive and vestibular effects of Magnetic Resonance Imaging related magnetic fields

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37345

Source
ToetsingOnline

Brief title
Acute neurocognitive and vestibular effects of MRI related MF

Condition

- Other condition

Synonym
healthy volunteers

Health condition

gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Magnetic Fields (MF), Magnetic Resonance Imaging (MRI), Neurocognition, Vestibular functioning

Outcome measures

Primary outcome

The test battery will include 9 different tests for e.g. motor functioning,

attention, concentration, orientation, (working) memory, vision and vestibular

functioning. Exposure of the subject to static and time-varying magnetic fields

will be measured with a small dosimeter that will be attached to the

participant*s head.

Secondary outcome

Sensitivity of the vestibular system will be defined by two clinical tests,

calorisation test and a rotary chair test.

Study description

Background summary

Previous studies showed acute subtle detrimental neurocogntive effects of movement in a static magnetic field of 1.5 T, 3 T and 7 T MRI scanners. In addition, an acute effect on postural sway was observed in our previous experiment, suggesting a change in vestibular function. These effects probably arise due to induced electrical currents that are generated during movement in the static magnetic fields in the vicinity of the scanners. However, it is not clear to what extend these effects are related to the static magnetic field or to time-varying magnetic field induced by movement in the static magnetic field. Furthermore, effects on postural stability (vestibular functioning) have not been shown before and should be replicated and further characterised.

Although the observed acute effects are subtle, they are relevant in clinical practice, since for example surgeons and radiologists working close to MRI systems need to maintain a high level of neurocognitive and postural performance.

Study objective

The main objective of this study is to gain more insight into the working mechanism of static magnetic fields alone, as well as in combination with movement-induced time-varying magnetic fields near MRI-scanners on neurocognitive and vestibular performance. In addition, we will correlate subjects* test results to the sensitivity of their vestibular system.

Study design

Double blind randomised crossover design

Study burden and risks

Subjects will be exposed to four experimental conditions; two exposure conditions with a static magnetic field of 1.0 T at the near end of a MRI bore (with and without additional head movements to induce time varying magnetic fields) and two control conditions without static magnetic fields (with and without additional head movements). The standardised short head movements will induce time-varying fields of around 2400 mT/s in the exposure condition and 0 mT/s in the control condition. These head movements will precede each test of the test battery.

Participants are requested to visit the UMCU on three occasions. During the first visit there is a practice session and two test sessions where they are subjected to test battery of 30 minutes (2 hours in total). In the second visit, two test sessions of 30 minutes each are assessed (1.5 hours in total). On the third day sensitivity of the vestibular system will be defined using standard clinical tests (1 hour). Potential short-term effects of exposure such as mild vertigo and nausea will probably last for a few minutes based on previous experience. No long-term effects of exposure to magnetic fields and vestibular sensitivity testing are known. A travelling allowance and a financial gift voucher of seventy-five euros* for three completed visits will be provided.

Contacts

Public
Universiteit Utrecht

Jenalaan 18D
3584 CK Utrecht
NL
Scientific
Universiteit Utrecht

Jenalaan 18D
3584 CK Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

helathy
men and women
between 18 and 65 years
level vulnerability for motion sickness

Exclusion criteria

MRI incompatible volunteers
neurological or psychiatric disorder (past or present)
Drug use in the last 4 weeks (except of contraception)

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2012
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	04-04-2012
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	NL39447.041.12