Test-retest reliability on ePOD fMRI studies

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To study the test-retest reliability effects on three fMRI tasks administered in the ePOD project in children (aged 10-14) and adults (aged 23-30).

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

Summary

ID

NL-OMON36088

Source
ToetsingOnline

Brief title
Test-retest fMRI

Condition

- Other condition

Synonym
Test-retest effect on fMRI

Health condition

het onderzoek betreft geen aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MRI, neuropsychological assessment, Test-retest

Outcome measures

Primary outcome

Difference in accuracy (ICC; intra-class correlation coefficients) between

first and second scanning session for voxels located within the activated

network.

Secondary outcome

N.a.

Study description

Background summary

When performing serial testing it is of crucial importance to know the occurrence of test-retest effects such as practice effects, and whether these differ between children and adults. However, there is limited literature on the re-test effects of task-related functional MRI (fMRI), particularly in children (Kelly and Garavan et al., 2005). The current project aims to study potential re-test effects on three fMRI tasks administered in the ongoing ePOD project. In the ePOD (effects of Psychotropic drugs On the Developing brain) project we investigate the effects of age following chronic treatment with fluoxetine (Prozac®) and methylphenidate (Ritalin®) in clinical trials in children, adolescents and young adults (NL. 26402.000.09 and NL 34509. 000.10).

Study objective

To study the test-retest reliability effects on three fMRI tasks administered in the ePOD project in children (aged 10-14) and adults (aged 23-30).

Study design

Non-invasive longitudinal two time point study

Study burden and risks

MRI itself is a non-invasive imaging modality, which is frequently employed also in healthy children aged 8 years and older in the Netherlands (Prof. Crone LUMC *Hersenen in actie*: http://www.juniorhersenen.nl/index.php/meedoen-aan-onderzoek) and also at the AMC (e.g., METC 06/207). The nature of the burden is classified as minimal, considering that subjects will have to come to the AMC for 45 minutes on two occasions. The risks involved are negligible, as all the techniques employed are registered for their use and/or routinely performed at the AMC.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

12 healthy girls aged 12-14 years
12 healthy young women aged 23-30 years
12 heathy boys aged 10-12 years
12 healthy young males aged 23-30

Exclusion criteria

A history of neuropsychiatric disease. Contraindications for MRI (e.g. osteosynthetic material, pacemaker, artificial cardiac valves); claustrophobia.

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):	01-04-2011
Enrollment:	0
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-04-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL35557.018.11