# fMRI-reference database for the clinic

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The study's objective is to create an fMRI-reference database in order to make neuroscientific knowledge easily applicable and accessible to the clinic.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Neurological disorders NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON42755

**Source**
ToetsingOnline

**Brief title**
fMRI-reference database

### Condition

- Neurological disorders NEC

**Synonym**
Healthy brain activity common tasks; Healthy brain activity to serve as a reference for the clinic.

**Research involving**
Human

### Sponsors and support

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

### Intervention

**Keyword:** database, fMRI, reference

## Outcome measures

### Primary outcome

De primaire outcomes are the fMRI-references per group and per task. The

reference is the average of individual 3D maps of T-statistics derived from the

MRI-signal in combination with the given task.

### Secondary outcome

The secundary outcomes are averaged (normalized) structural/anatomical

MRI-images per group.

# Study description

### Background summary

Many patients undergo surgical treatment every year in the clinic of neurology and neurosurgery. It is often desirable to assess the organization of brain structures on the basis of function. It allows the medical experts to determine the best strategy for a certain patient, such as operating while the patient is awake or location where the skull should opened to minimize risks of loss of function.

Functional MRI (fMRI) is well-suited to satisfy these demands. However, fMRI requires expert knowledge during task development, analysis as well as the interpretation of functional MR-scans. In order to comply with the demands from the clinic of neurology and neurosurgery of the UMC Utrecht, it is desirable to create a fMRI-reference database based on standardized tasks. The database would allow the practitioner to easily identify (abnormalities of) functional brain structures. The reference database would also allow for a quality assessment of the acquired functional MR-scans.

### Study objective

The study's objective is to create an fMRI-reference database in order to make neuroscientific knowledge easily applicable and accessible to the clinic.

### Study design

The creation of an fMRI-reference database, involving the scanning of healthy volunteers, is purely descriptive. The aim of the study is to create references for fMRI-data that are representative for a number of specific tasks.

To create the references, healthy volunteers will undergo several brain scans: 3 structural images: T1-, T2-, and DTI-weighted images, and series of functional brain scans acquired during 9 tasks. The tasks are: hand-motor (2x), foot-motor (2x), mouth-motor, verb generation (language), picture naming, working memory, and 'resting state'.

### Study burden and risks

There are no known risks of fMRI as it does not make use of contrast agents, etc. The fMRI-procedure is painless and not uncomfortable. Participants will be asked to lie still during approximately 1 hour and a maximum duration of 90 minutes, which has been shown to be an acceptable time duration for fMRI experiments. The tasks are relatively simple and not exhausting. Therefore, the burden and risks associated with participation are minimal.

## 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

18 years or older
Right handed
Normal or correct to normal vision (contact lenses are allowed)

## Exclusion criteria

Treated for neurological or psychiatric disorders
Use of painkillers or antihistamine
Claustrophobia
Pregnant

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 25-04-2016 |
| Enrollment: | 84 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 23-12-2015 |
| Application type: | First submission |
| Review commission: | METC NedMec |

## 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 | NL54601.041.15 |