

# Reconstruction of the optic radiation using enhanced DTI compared to HARDI

Published: 14-03-2014

Last updated: 24-04-2024

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Neurological disorders NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON40269

### Source

ToetsingOnline

### Brief title

Reconstruction of the Meyer's loop

### Condition

- Neurological disorders NEC

### Synonym

Epilepsy, falling sickness

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Epilepsiecentrum Kempenhaeghe

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Enhanced DTI, HARDI, Optic Radiation, Tractography

## Outcome measures

### Primary outcome

An estimate of the anatomically plausible OR tracts for the three datasets as described earlier, which is based on the percentage of fibers that remain after all implausible OR tracts are removed from those produced by the probabilistic tracking algorithm.

### Secondary outcome

As secondary study parameter the plausibility of the fiber distribution will be evaluated compared to the anatomy.

## Study description

### Background summary

In case of refractory localized temporal lobe epilepsy the anterior part of the temporal lobe and parts of the mesial structures can be removed with an anterior temporal lobe resection. After surgery approximately 60 to 80% of the patients become seizure free. However, a visual field deficit in the upper quadrant of the visual field is a complication that might arise due to disruption of the most anterior part of the optic radiation (Meyer\*s loop), even according to some publications in up to 100% of the cases. Since a large inter-subject variability exists in the anterior extent of Meyer\*s loop, assessment of the risk of a visual field deficit is complicated and therefore accurately localizing and visualizing the optic radiation (OR) is useful. Previous research has shown that the reconstruction of the OR is possible by using anatomical MRI acquisition techniques for fiber tracking (diffusion-weighted tractography). It has furthermore been demonstrated that using special analysis techniques to process these data improves the reconstruction of the OR.

### Study objective

In this study the potential of using the enhanced procedures for analyzing diffusion weighted data which were acquired according to clinical procedures is further investigated. The result is compared to the reconstruction of the OR based on high resolution diffusion-weighted tractography data, what takes much longer to acquire and therefore, is not suited for clinical use.

## **Study design**

This is a feasibility study wherein ten healthy volunteers will undergo a short anatomical scan acquired according to the current clinical protocol with a limited number (32) of diffusion directions and a high resolution diffusion-weighted scan (with 128 diffusion directions). fMRI activated upon visual stimulation is used to delineate the primary visual cortex. The diffusion-weighted data are processed, resulting in three distinct datasets: diffusion-weighted data acquired with the clinical protocol and analyzed according to the standard and to the enhanced analysis procedures and diffusion-weighted data acquired with the high resolution scan. For these datasets white matter fibers connecting the visual cortex and the lateral geniculate nucleus are generated for each of the conditions using a probabilistic fMRI seeded tractography algorithm. Since there is no ground truth for white matter fiber tracts a plausibility evaluation procedure will be applied, which is based on a pre-postoperative comparison study of the OR.

## **Study burden and risks**

The volunteers will undergo one MR scanning session (about 60 minutes in duration). The extra risk for the participants in this study is negligible.

## **Contacts**

### **Public**

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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 and < 65 years;
- \* no structural abnormalities based on earlier MR scans;
- \* no suspicion of further neurological disorders.
- \* written agreement that unexpected findings will be reported to the person (general practitioner or other medical specialist) as indicated by the volunteer on the MRI checklist;
- \* subjects should give a written informed consent. The informed consent gives each participant thorough understanding of the purpose, nature and procedures of the examinations and explains the voluntariness of the examinations and the confidentiality of the patients data.

### Exclusion criteria

- \* who cannot meet the mild physical or psychological criteria for prolonged MRI scanning;
- \* who have a cardiac pacemaker or intracranial metals.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 08-09-2014  
Enrollment: 10  
Type: Actual

## Ethics review

Approved WMO  
Date: 14-03-2014  
Application type: First submission  
Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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	NL43386.068.13