# Feasibility of Diffusion Tensor Imaging MRI in post-polio syndrome

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Viral infectious disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON38530

**Source**
ToetsingOnline

**Brief title**
DTI in PPS

### Condition

- Viral infectious disorders
- Muscle disorders
- Neuromuscular disorders

**Synonym**
Post-polio syndrome

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** Diffusion Tensor Imaging (DTI), Magnetic Resonance Imaging (MRI), Post-polio Syndrome (PPS)

## Outcome measures

### Primary outcome

Main study endpoint will be a characterization of changes in DTI parameters of

affected muscles, isometric muscle strength measurements (quadriceps) and a

full picture of the architectural organization of lower limb muscles and the

leg as a whole.

### Secondary outcome

n/a

# Study description

### Background summary

Post-polio syndrome (PPS) is a condition that affects polio survivors years after recovery from an initial acute attack of the poliomyelitis virus. In 2010, 12-20 million people worldwide suffered from late sequelae of poliomyelitis. One of the main symptoms is progressive muscle weakness. Besides physical problems, patients also deal with mental fatigue and lower quality of life.
The pathophysiological mechanism behind PPS is not fully understood, and there is no specific treatment. Therapeutic interventions are mainly focused on adaptive measures, physical therapy and symptom relief. Pharmacological treatments are still experimental.
There is great need for quantitative information on the disease progression and the process of skeletal muscle plasticity, which can consequently improve treatment monitoring and enable intensified tailored physical therapy.
Diffusion Tensor Imaging (DTI) is a Magnetic Resonance Imaging (MRI) technique that is able to characterize muscle and nerve fiber architecture as well as to provide insights in local histopathological status of nerve and muscle tissue.

### Study objective

The main objective of this study is to compare DTI findings of PPS patients with those of healthy controls. Secondary objective of this study is to correlate DTI findings with clinical data such as isometric muscle strength. Third objective is to define the reproducibility of DTI in muscle tissue.
In this research we do not aim to replace isometric strength measurements by DTI, but to assess the feasibility of DTI as a tool to provide quantitative and reproducible information on the disease progression and skeletal muscle plasticity, as well as to improve knowledge on the pathophysiology of PPS.

### Study design

Observational study

### Study burden and risks

Patients will undergo and MRI scan of the legs twice and isometric muscle strength testing of the quadriceps once (approximately 1 hour per part). Study subjects have to visit the AMC twice. Burden for study subjects is minimal.

Isometric muscle strength measurements do not pose any risk to the study subjects.
Risks for subjects undergoing MRI examination are minimal, provided precautions have been made to prevent examining individuals with contraindications. For this purpose, the routine MRI contra indications form of the AMC will be used. If the subject has a prosthesis, he/she is only included if the prosthesis serial number can be acquired since recent prostheses are not a contraindication for MRI.

## 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

PPS patients:
Subject has symptomatic quadriceps deterioration, evidence of enlarged motor units (as measured by high-density surface EMG) and isometric quadriceps muscle strength of >=30Nm in at least one leg. Subject has symptoms for >= 1 year that cannot be explained by any other neurological disorder
Healthy controls: Subject is free of symptoms that can be explained by any neurological disorder

## Exclusion criteria

PPS patients & healthy controls:
Subject is unwilling or unable to participate in this study and to give informed consent. Subject is also excluded if prosthesis registration number cannot be acquired (relatively new prostheses are not a contra-indication for MRI, this can be checked with the prosthesis registration number) (If applicable). Other exclusion criteria are contra-indications to undergo an MRI scan (pregnancy, claustrophobia, metal corpora aliena or metal implants such as pacemakers)

# Study design

## Design

Study type: Observational non invasive

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| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

### Recruitment

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| Recruitment status: | Will not start |
| Enrollment: | 30 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 26-04-2013 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 | NL43077.018.12 |