# Long term follow-up of PLS-patients: cognitive aspects and reliability of the diagnose

Published: 15-06-2016
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Main objective: - Obtain long-term clinical follow-up data in PLS patients to investigate the reliability of the diagnosis PLS. - Obtain data on cognitive functioning to investigate the possible relation between PLS and FTD.Secondary objectives: -...

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

## Summary

### ID

NL-OMON43298

**Source**
ToetsingOnline

**Brief title**
Long term follow-up of PLS-patients

### Condition

- Neuromuscular disorders

**Synonym**
PLS, Primary lateral sclerosis

**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:** Cognitive, FTD, PLS

## Outcome measures

### Primary outcome

Reliability of the diagnose will be tested by use of anamnesis, neurological examination and genetic research.

Cognitive and behavioural functioning will be assessed and explored using the ECAS, ALS-FTD-Q, FAB and HADS rating scales. Neuropsychological evaluation will be performed.

### Secondary outcome

Physical deterioration and functioning of the patient will be measured by use of the MRC-scores used during the neurological investigation and the ALS-FRS scale.

# Study description

### Background summary

We know that the reliability of the diagnosis PLS(primary lateral sclerosis) increases with the duration of the symptoms. As PLS can develop into ALS (amyotrophic lateral sclerosis), which has a worse outcome, it is beneficial for the patient to have more certainty about the diagnose. Possibly long term follow-up data can create insight in long-term conversion to ALS (or other diagnoses).

Also, recently multiple cases of FTD (frontotemporal dementia) and PLS have been identified. As a relation between ALS and FTD is already well established, we need to further examine the relation between PLS and FTD.

### Study objective

Main objective:
- Obtain long-term clinical follow-up data in PLS patients to investigate the reliability of the diagnosis PLS.
- Obtain data on cognitive functioning to investigate the possible relation between PLS and FTD.
Secondary objectives:
- Investigate whether the ALS and FTD related genetic mutation C9orf72, is also prevalent in a PLS population (with or without cognitive deficits).
- Save samples for future research.

### Study design

The study has an observational character and consists of a single follow-up of PLS patients who were studied in the period of 2003-2006.

### Study burden and risks

Participation is limited to one visit with a duration of approximately 2 * hours. Patients will be visited at their residential location, or in the UMC Utrecht if preferred. Neurological investigation, the FVC (a short pulmonary functioning test) and multiple interviews and a neuropsychological evaluation will be performed. Two tubes of 10-ml blood will be drawn in total.

## 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

Participation of the former PLS related study of 2003-2006
Age 18-years or above.

### Exclusion criteria

None.

## 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): | 04-08-2016 |
| Enrollment: | 55 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 15-06-2016 |
| 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 | NL57082.041.16 |