# Brain Structure and Development in Children and Adolescents with Prader-Willi Syndrome: A Combined Structural and Functional MRI Study

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We aim to document the brain anatomy and functioning and development of children and adolescents of different ages who suffer from Prader-Willi syndrome in order to gain insight into the possible relation between the observed behavior and the brain...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Chromosomal abnormalities, gene alterations and gene variants |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON39422

**Source**
ToetsingOnline

**Brief title**
Brain Structure and Development in Children with Prader-Willi Syndrome

### Condition

- Chromosomal abnormalities, gene alterations and gene variants

**Synonym**
Prader-Willi Syndrome

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Stichting Kind en Groei

## Intervention

**Keyword:** MRI, Prader-Willi syndrome

## Outcome measures

### Primary outcome

We will measure multiple parameters such as total brain volume, grey matter/white matter volume, volumes of various brain structures (such as pituitary gland, caudate nucleus, hippocampus, hypothalamus), white matter connections (corpus callosum, anterior and posterior commisures), connectivity within the different lobes. We will further investigate the known functional networks within the brain by means of resting state fMRI. Longitudinal changes in structure and function will be assessed as well.

### Secondary outcome

not applicable

# Study description

### Background summary

Brain structure and development in children and adolescents with Prader-Willi syndrome: a combined structural and functional MRI study

In the previous studies within our group we gathered a lot of data about children and adolescents with Prader-Willi syndrome, such as weight, length, endocrine markers, sleep disturbances which has led to the improvement of the treatment of children and adolescents with Prader-Willi syndrome. However, until now there were no studies conducted that addressed the anatomy and development of the brain of children and adolescents with Prader-Willi syndrome.

### Study objective

We aim to document the brain anatomy and functioning and development of children and adolescents of different ages who suffer from Prader-Willi syndrome in order to gain insight into the possible relation between the observed behavior and the brain anatomy.

### Study design

Observational/comparative longitudinal study

### Study burden and risks

The risks associated with MRI research are not reported yet and the burden caused by MRI noise is minimized.

## Contacts

**Public**
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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

Children and adolescents with genetically confirmed PWS and known genetic defect between 6-25 years old and healthy age- and sex-matched controls
Written Informed consent of the caregivers and children and adolescents older than 12 years and assent of patients/children younger than 12 years
Written informed consent of healthy adult controls
Successful completion of the mock MRI scanner protocol for healthy controls under 12 years old

### Exclusion criteria

Other chromosomal abnormalities
Claustrophobia
Contra-indications for MRI scanner
The use of medication for treating anxiety, mood disorders or psychiatric disturbances including the regular use of homeopathic St John*s wort preparations for longer than two weeks
Expected or proven non-compliance

## Study design

### Design

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

### Recruitment

NL
Recruitment status: Recruiting

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|---|---|
| Start date (anticipated): | 14-11-2010 |
| Enrollment: | 160 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 11-10-2010 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 23-08-2011 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 01-11-2013 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## 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 | NL32706.078.10 |