

# Assesment of tools regarding the quality and effect control of brace treatment for idiopathic scoliosis

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The purpose of this study is to evaluate the quality and effect of scoliosis brace treatment, by means of correlating body brace interface pressure and scoliosis correction in combination with quality of life questionnaires.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31436

### Source

ToetsingOnline

### Brief title

PQSB

### Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

### Synonym

lateral curvature of the spine

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Ziekenhuis Maastricht

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

## Intervention

**Keyword:** Brace treatment, Evaluation Study, Idiopathic scoliosis, interface pressure

## Outcome measures

### Primary outcome

One interface pressure measurement session

two successive quality of life questionnaires

### Secondary outcome

Optimalisation scoliosis brace treatment.

## Study description

### Background summary

Idiopathic scoliosis is a relatively common deformation starting with or just before the growth spurt. Brace treatment is used to prevent progression and if possible correction of the scoliosis. In order to achieve a good result the brace should be worn for 23 hours, and during the whole growth period. Patients are predominantly girls in the age between 8 to 16 year old. The long treatment in combination with the difficult age of the patients makes sufficient compliance a challenge.

### Study objective

The purpose of this study is to evaluate the quality and effect of scoliosis brace treatment, by means of correlating body brace interface pressure and scoliosis correction in combination with quality of life questionnaires.

### Study design

Single centre, single measurement, non-randomised observational study.

### Study burden and risks

One non invasive, risk less interface pressure measurement session lasting for 30 minutes, subsequently after the regular scoliosis outpatient clinic visit. During this session, the patient has to assume different postures, mimicking

daily activity. Two quality of life questionnaires are send to the patient with a three month interval, completing these questionnaires will take approximately 15 minutes. The total extra time is 60 minutes. The correction of the scoliosis is measured on the regular control X-rays.

## Contacts

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adolescents (12-15 years)  
Adolescents (16-17 years)  
Children (2-11 years)

### Inclusion criteria

Patients with idiopathic scoliosis, who are indicated for a scoliosis brace.  
Cobbs angle between 20° - 40° at start of treatment.  
Male and female patients  
Patients who read and understand the METC approved patient information  
Patients who are willing to participate and have written permission from their parents /

guardians.

## Exclusion criteria

Patients requiring surgical treatment. (Cobbs angle >40°)  
Patients with other back problems  
Patients with spine operations in the past  
Patients with neurological signs  
Patients willing, but without parental / guardian permission  
Patients without a working knowledge of Dutch

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-01-2008

Enrollment: 27

Type: Anticipated

## Ethics review

Approved WMO

Date: 19-01-2009

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	NL20510.068.07
Other	NTR (TC = 1247)