

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24452

### Source

Nationaal Trial Register

### Brief title

PQSB

### Health condition

body brace interface pressure  
quality of life questionnaire

## Sponsors and support

**Primary sponsor:** Maastricht Academic Hospital

**Source(s) of monetary or material Support:** Maastricht Academic Hospital

## Intervention

## Outcome measures

### Primary outcome

To improve brace treatment for idiopathic scoliosis, by means of comparing body brace interface pressure with measured Cobbs angles on the control X-rays in combination with

reported quality of life.

## **Secondary outcome**

Optimize the scoliosis brace treatment to the individual situation of each scoliosis patient by applying body brace interface pressure measurements as well as the brace questionnaire in the regular care for patients with idiopathic scoliosis.

# **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.

The purpose of this single centre, single measurement, non-randomised, observational 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.

Patients with idiopathic scoliosis treated with a scoliosis brace, between the age of 8 and 16 year old, will be included for one interface pressure measurement session and two successive sets of quality of life questionnaires.

## **Study objective**

The combination of body brace interface pressure measurements and quality of life questionnaires will improve brace treatment in patients with idiopathic scoliosis

## **Study design**

After inclusion the pressure measurement will take place as well as completing the first quality of life questionnaire on the first following regular control visit to the orthopaedic outpatient clinic. 3 month later the second quality of life questionnaire will be completed

## **Intervention**

Body brace interface pressure measurements

Quality of Life questionnaires

## Contacts

### **Public**

Orthopaedic department  
Maastricht Academic Hospital  
Postbus 5800

L.W. Rhijn, van  
Maastricht 6202 AZ  
The Netherlands

### **Scientific**

Orthopaedic department  
Maastricht Academic Hospital  
Postbus 5800

L.W. Rhijn, van  
Maastricht 6202 AZ  
The Netherlands

## Eligibility criteria

### **Inclusion criteria**

1. Patients with idiopathic scoliosis, who are treated with a scoliosis brace
2. Male and female patients
3. Cobbs angle between 20o-40o at start of treatment
4. Patients who read and understand the METC approved patient information
5. Patients who are willing to participate and have written permission from their parents / guardians

### **Exclusion criteria**

1. Patients requiring surgical treatment (Cobbs angle >40o and progression)
2. Patients with other back problems
3. Patients with spine operations in the past

4. Patients with neurological signs
5. Patients willing, but without parental / guardian permission
6. Patients without a working knowledge of Dutch

## Study design

### Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	27
Type:	Anticipated

## Ethics review

Not applicable	
Application type:	Not applicable

## 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
NTR-new	NL1202
NTR-old	NTR1247
Other	MEC azM/UM : 07-2-106
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A