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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24452

Source
NTR

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 folowing 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

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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