A comparison between two bracing methods in idiopatic scoliosis: the Boston and a new developed brace.

No registrations found.

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

Summary

ID

NL-OMON29387

Source
Nationaal Trial Register

Brief title
N/A

Health condition

- correction measured with spinal x-rays in the two braces
- correction force of the braces measured with presuure measurements

Sponsors and support

Primary sponsor: Pieken in de Delta
Source(s) of monetary or material Support: Ministery of economics

Intervention

Outcome measures

Primary outcome

Our primary objective is to compare the two braces, the classic Boston brace and new developed brace, by means of comparing body brace interface pressure and measured Cobbs

angles on the control X-rays.

Secondary outcome

Our secondary objective is optimize the scoliosis brace treatment to the individual situation of each scoliosis patient by applying body brace interface pressure measurements as well as the Cobbs angles correction in patients with idiopathic scoliosis.

Study description

Background summary

Compliance is necessary to have good results with brace treatment in idiopathic scoliosis. therefore we have developed a brace with probably a higher acceptance and comfort by giving more freedom of motion and a bace closure in front of the brace. We want to test the effectiveness of the new developed brace with the most used boston brace. This is performed with spinal x-rays and pressure measurements.

Study objective

The new brace is efficient in correcting of idiopathic scoliosis compared to the Boston brace measure with spinal x-rays and pressure measurements.

Study design

Two months.

Intervention

1. Conventional spinal x-rays;

2. Pressure measurements.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with adolescent idiopathic scoliosis (age 12-16 yrs), 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 with allergy of components of the brace or pressure measurement device;

6. Patients willing, but without parental / guardian permission;

7. Patients without a working knowledge of Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-06-2009
Enrollment:	6
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	NL1705
NTR-old	NTR1815
Other	MEC MUMC : 09-2-029
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A