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

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The purpose of this study is to compare two different braces in idiopatic scoliosis, by means of body brace interface pressure measurements and conventional spinal x-rays (anterior-posterior).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32933

Source
ToetsingOnline

Brief title
comparison of two scoliosis bracing methods

Condition

- Other condition
- Musculoskeletal and connective tissue disorders congenital

Synonym
idiopathic scoliosis

Health condition

idiopathische scoliose

Research involving
Human

Sponsors and support

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

Intervention

Keyword: brace, compliance, pressure, scoliosis

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

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 and therefore effectiveness a challenge. Therefor our group, TNO (organisation for science projects), Welldesign (industrial designer), IDEE (Instrument Development Engineering & Evaluation), Orthopaedie 2000 (orthopaedic instrumentmaker)and department Orthopaedic Surgery of the Academic Hospital Maastricht, developed a brace to get an higher compliance with the

same or better correction of the scoliosis.

Study objective

The purpose of this study is to compare two different braces in idiopatic scoliosis, by means of body brace interface pressure measurements and conventional spinal x-rays (anterior-posterior).

Study design

Single centre, single measurement, non-randomised observational study

Intervention

- spinal X-rays with each 0,135mSv
- non-invasive pressure measurements with NOVEL pressure measurement device

Study burden and risks

One non invasive, risk less interface pressure measurement session in each brace lasting for 30 minutes, subsequently after or during the regular scoliosis outpatient clinic visit. During this session, the patient has to assume fifteen different postures, mimicking daily activity. The correction of the scoliosis is measured on the spinal X-rays, which will be planned before the pressure measurements. The total extra time is about 60 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

- Patients with idiopathic scoliosis, who are treated with a scoliosis brace.
- Male and female patients
- Cobbs angle between 20o-40o at start of treatment.
- Patients who read and understand the METC approved patient information
- Patients who are willing to participate and have written permission from their parents / guardians.
- Patients in the age of 12-16 yrs

Exclusion criteria

- Patients requiring surgical treatment. (Cobbs angle >40o and progression)
- 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: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2009
Enrollment:	6
Type:	Actual

Medical products/devices used

Generic name:	new developed scoliosis brace
Registration:	No

Ethics review

Approved WMO

Date:	14-07-2009
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	NL26949.068.09

Register	ID
Other	TC1815