

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

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29387

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

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

Ondersteuning

Primaire sponsor: Pieken in de Delta

Overige ondersteuning: Ministry of economics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Two months.

Onderzoeksproduct en/of interventie

1. Conventional spinal x-rays;
2. Pressure measurements.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 20°-40° 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients requiring surgical treatment (Cobbs angle >40° 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	09-06-2009
Aantal proefpersonen:	6
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1705
NTR-old	NTR1815
Ander register	MEC MUMC : 09-2-029
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A