

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

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

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

Samenvatting

ID

NL-OMON24452

Bron

NTR

Verkorte titel

PQSB

Aandoening

body brace interface pressure
quality of life questionnaire

Ondersteuning

Primaire sponsor: Maastricht Academic Hospital

Overige ondersteuning: Maastricht Academic Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Body brace interface pressure measurements

Quality of Life questionnaires

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

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 willing, but without parental / guardian permission
6. Patients without a working knowledge of Dutch

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2008
Aantal proefpersonen:	27
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	NL1202
NTR-old	NTR1247
Ander register	MEC azM/UM : 07-2-106
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A