Effect of in- and outpatient brace adaptation protocols on brace compliance in adolescent patients with idiopathic scoliosis

Published: 29-05-2015
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The objective of this study is to evaluate whether an in- or outpatient initiation of the brace treatment has an influences short and long term brace compliance.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON41782

Source
ToetsingOnline

Brief title
Brace pilot study

Condition

- Bone disorders (excl congenital and fractures)

Synonym
curved spine, scoliosis

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Anna Fonds

Intervention

Keyword: Adaptation protocol, Adolescent idiopathic scoliosis, Boston brace, Compliance

Outcome measures

Primary outcome

The primary outcome parameter is short and long term brace compliance as measured by a temperature logger in the brace. The temperature logger will be programmed to store the date time and temperature every 20 minutes. The sensor has been validated in the past in which a temperature between 32.2 and 37.2 indicates that the brace is worn.

Secondary outcome

Secondary outcome parameters are welbeiing of the AIS patients as measured by the PedsQL and SRS-22

Study description

Background summary

In the past, there has been a lot of debate about the effectiveness of brace treatments for adolescent idiopathic scoliosis (AIS). Recently, the Bracing in Adolescent Idiopathic Scoliosis Trial made an important contribution to this continueing debate as they showed that bracing significantly reduces the risko of progression and the subsequent risk to undergo surgery. However, the benefit of bracing significantly increases with longer hours of brace wear. Few children with AIS wear the brace for the prescribed number of hours per day. Since the brace has to be word for 20 hours a day over a long period of time, the bracing has a significant impact on dayly life of AIS patients. Initiation of the brace treatment is done differently in scoliosis centers world wide. It can be done in an in and outpatient setting. Whether the setting in which the brace treatment is initiated influences the short and long term compliance is unknown.

Study objective

The objective of this study is to evaluate whether an in- or outpatient initiation of the brace treatment has an influences short and long term brace compliance.

Study design

A prospective observational cohort design is used in which we compare the standard care given in 4 different hospitals. Two of these hospitals have the same outpatient initiation protocol for brace treatment whereas the other two hospitals have the same inpatient initiation protocol.

Study burden and risks

The patients receive the standard care in the hospitals. There are no additional risks related to this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Patients 10 years or older with an idiopathic adolescent scoliosis with an indication for brace treatment who have not had an operative treatment for scoliosis in the past

Exclusion criteria

- Scoliose with the apex of the curve proximal to T7
- A previous brace treatment for scoliosis
- A previous surgical treatment for scoliosis
- Patients who are not able to fill in the questionaires

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-06-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	29-05-2015

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL50853.100.14