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

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27973

Source
NTR

Brief title
BRACE

Health condition

Adolescent idiopathic scoliosis, AIS, scoliosis, Boston brace, compliance, adaptation protocol, Adolescente idiopathische scoliose

Sponsors and support

Primary sponsor: OLVG, Department of Orthopedic Surgery
Source(s) of monetary or material Support: Anna Fonds

Intervention

Outcome measures

Primary outcome

-Compliance (measured by a thermo sensor)

-Well-being patient (PedsQL, SRS-22)

-Well-being parents (PedsQL Inventory family module, Child competency inventory)

Secondary outcome

-Relation compliance and well-being

-cobb¡¯s angle over time

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 risk of progression and the subsequent risk to ondergo surgery. However, this benefit of bracing was only achieved with good compliance (i.e. many 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 worn for 20 hours a day over a long period of time, the bracing has a significant impact on daily 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. The objective of this study is to evaluate the effect of in- and outpatient brace adaptation on short- and long-term brace compliance.

Study objective

An inpatient brace adaptation protocol increases therapy compliance and brace comfort for the patient compared to an outpatient brace adaptation protocol.

Study design

Start bracing is considered enrollment (T=0). Outpatient clinic visits at 2 months and 6 months. After 6 months the visits are every 6 months. Last visit is at stop brace treatment when skeletal maturity is reached (T=e)

Intervention

outpatient brace adaptation or inpatient brace adaptation

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

-Female patients with adolescent idiopathic scoliosis

-Age ¡Ý10 en ¡Ü13 years

-Lenke type 1

-Coronal Cobb angle of ¡Ü 50¡ã

-Pre-menarche

Exclusion criteria

-Scoliosis with the apex of the curve proximal to T7

-Prior surgery to the spine

-prior brace treatment for scoliosis

-Patients who don't have the ability to read and write in the Dutch language

-Patients who are unwilling to cooperate with the study protocol and follow-up schedule.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	26-02-2016
Enrollment:	40
Type:	Unknown

Ethics review

Positive opinion

Date:	15-08-2016
Application type:	First submission

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	NL5776
NTR-old	NTR6059
Other	MEC-U : R15.001

Study results