

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

Gepubliceerd: 15-08-2016 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27973

Bron

NTR

Verkorte titel

BRACE

Aandoening

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

Ondersteuning

Primaire sponsor: OLVG, Department of Orthopedic Surgery

Overige ondersteuning: Anna Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Compliance (measured by a thermo sensor)

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

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

outpatient brace adaptation or inpatient brace adaptation

Contactpersonen

Publiek

[default]

The Netherlands

Wetenschappelijk

[default]

The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Female patients with adolescent idiopathic scoliosis
- Age ≥10 en ≤13 years
- Lenke type 1
- Coronal Cobb angle of ≥ 50°
- Pre-menarche

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Parallel
Toewijzing: Niet-gerandomiseerd
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Anders
(Verwachte) startdatum: 26-02-2016
Aantal proefpersonen: 40
Type: Onbekend

Ethische beoordeling

Positief advies
Datum: 15-08-2016
Soort: Eerste indiening

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	NL5776
NTR-old	NTR6059
Ander register	MEC-U : R15.001

Resultaten