Aspects of bracing in adolescent idiopathic scoliosis

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Objective: The primary objective of the study is determining the contributing factors in bracing for AIS. The contributing factors are determined as factors of influence in the corrective possibilities and therefore end...

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational non invasive

Summary

ID

NL-OMON23817

Source
Nationaal Trial Register

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Health condition

Adolescent idiopathic scoliosis

Research involving
Human

Sponsors and support

Primary sponsor: None (pending)
Source(s) of monetary or material Support: MUMC+, department of orthopedics

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

The main objective of the study is to quantify the effect of conservative treatment of AIS with the use of the new developed Maastricht brace (ABR 09-02-029) by determining the deformation of cobb's angle over time, using longitudinal radiological assessment with use of anteroposterior and lateral full spine radiographs.

Secondary outcome

Secondary Objectives:

• Compliance in brace treatment for AIS Using an incorporated thermo sensor in the brace to objectify actual brace wearing by the patients.

• Pulmonary function in thoracolumbar brace Brace wear should result in changes in pulmonary function, predictable in nature. Pulmonary function at end point of brace wear comparable to healthy subject. (compared to non-brace wear)

• Pressure measurements in brace Is the brace able to apply the requested amount of force

• Motion analysis in brace (VICON)

Is the brace allowing the patient to demonstrate a normal walking pattern compared to healthy subjects

Study description

Background summary

Rationale: Our rationale for the study is multi-layered. Brace treatment is only effective if the patient is compliant; an optimally constructed brace is not effective if only worn for two hours a week. The Maastricht brace was developed to increase compliance by optimizing wearability and therefore more comfort, while obtaining the same pressure and therefore effect as the current golden standard in the Netherlands, the Boston brace. Initial results are promising and further effects need to be objectified. As thoracic parts of the Maastricht brace are flexible, we expect pulmonary function to improve compared to previously reported pulmonary function in a Boston brace. Motion analysis within a thoracolumbar

brace is rarely described. With adequate placement and optimal fitting we expect to obtain a gait analysis close to the normal population. With this study we would like to develop an optimal treatment plan for AIS and obtain more insight in the pathophysiology of AIS and the effects (or effectiveness) of bracing.

Study objective
Objective: The primary objective of the study is determining the contributing factors in bracing for AIS. The contributing factors are determined as factors of influence in the corrective possibilities and therefore end term results of the M-brace, which are currently unknown. The contributing factors are listed as secondary objectives together with patient characteristics such as length and weight. The effect of contributing factors is quantified in changes of Cobb's angle over time. Secondary objectives are compliance of bracing using thermal sensors (Orthotimer), pulmonary function and development of pulmonary restriction in brace, motion analysis of gait impairment (CAREN) before, during and after bracing and pressure (Pressure Guardian) applied by the brace itself during bracing.

Study design
prospective cohort

Intervention
Maastricht brace

Study burden and risks
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden associated with participation is as follows (Table 1, Appendix 1):

1. An increase of time in every outpatient clinical visit to evaluate brace compliance with use of the Orthotimer and Pressure Guardian (Appendix 2).

a. Reading the sensors (both the Orthotimer and Pressure Guardian) will take place at the outpatient clinic and lasts about five minutes.

2. After an adequate brace placement of the initial brace there is an additional pulmonary test (+-2 hours) and an additional motion analysis (+-2 hours). These tests are non-invasive, but they do however consume half a day in total. These tests are to be repeated every year until endpoint of bracing at full bone maturity.

a. In summary both the pulmonary tests and the motion analysis will be taken every year and at start- and endpoint of brace treatment.

3. There is only one group of patients subject for these tests, there is no control group. There are no risks of attending. Treatment with the Maastricht brace and outpatient clinical controls are identical to current clinical practice in adolescent idiopathic scoliosis.

4. Additional questionnaires (two) are filled in every three months at the outpatient clinic. The average time investment is 15 minutes per visit.

Contacts

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Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (12-15 years)
Adolescents (16-17 years)
Adolescents (16-17 years)

Inclusion criteria

1. AIS

2. Indication for conservative treatment

3. Age above 12 years old

4. Eligible for follow up

5. Ability to read and write in the Dutch language

6. Patient who are physically and mentally willing and able to comply with the functional evaluation

Exclusion criteria

1. Prior surgery to the spine

2. Morbid obesity (BMI>35)

3. Any musculoskeletal or neurological (congenital) disorder

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

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Supportive care

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2018
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	21-01-2016
Application type:	First submission
Review commission:	METC Academisch Ziekenhuis Maastricht / Universiteit Maastricht

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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	NL5082
NTR-old	NTR5214
Other	NL53296.068.15

Study results

Summary results
Schrander et al. Scoliosis 2014, 9(Suppl 1):O34