How effective is a full-time brace when lying supine, compared to a dedicated night- time brace?

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To quantify how much a full-time brace corrects the spine in 3D in AIS patients when supine, compared to a dedicated night-time brace.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational invasive

Summary

ID

NL-OMON56649

Source
ToetsingOnline

Brief title
3D SPINE WP2

Condition

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

Synonym
abnormal spinal growth, Scoliosis, spinal deformity

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Inspine BV,MRIguidance ,MRIguidance en Inspine

Intervention

Keyword: AIS, Brace treatment, Intervertebral disc, MRI

Outcome measures

Primary outcome

- Cobb angle correction in percentage (%)

Secondary outcome

- Correction of Cobb angle of secondary curves

- Correction of Apical vertebral rotation: relative to the sacrum

- Change in Thoracic kyphosis: T4-T12.

- Change in Lumbar lordosis: L1-S1

- Position, shape and volume of both the nucleus pulpous and annulus fibrosus.

Study description

Background summary

Adolescent Idiopathic scoliosis (AIS) is a three dimensional (3D) spinal deviation from normal growth of the spine and trunk, with a prevalence of 2-4% in the general population that may interfere with normal cardio-pulmonary development. Its management depends on the magnitude of the spinal curvature, as expressed by the Cobb angle, and by maturation status mainly assessed by the Risser method, which uses the iliac crest maturation. Observation is indicated for mild curves and brace treatment is normally recommended for curves between 20° and 40° of Cobb angle, while bigger curves often require surgery. Although the effectivity of brace treatment has long been debated, there is now Level-1 evidence that braces can modify the natural history of AIS in a positive way. There are many braces on the market and all of them apply different degrees of external corrective forces to the trunk to correct the complex spinal deformity. Most braces are designed to be worn at least 18-20 hours per day, but evidence is increasing that dedicated night-time braces work very effectively. A possible explanation for the similar effectiveness of full time versus night-time braces could be that full time braces, that are measured, applied and checked with the patient upright, provide (much) less correction than expected when the patient lies down. This would mean that the spine is not

well corrected during the many hours that the child is in bed. There is therefore a need to elucidate the correction of the full-time brace provides when laying down.

Understanding the effectiveness of full-time braces in both upright and supine positions is therefore crucial. While correction in the upright position is widely studied for full-time braces, the impact of laying down on these braces' corrective mechanism remains unknown while it has been demonstrated that spinal morphology changes in the supine position compared to upright. This study aims to address this knowledge gap. Although full-time braces like the Cheneau brace are prescribed for 18-21 hour wear, data on their efficacy in the supine position is lacking. We hypothesize that, due to the altered spine shape in the supine position, the additional correction provided by this type of brace may be limited. This could explain why dedicated night-time braces, which are also much better accepted by the adolescent patient, have shown comparable results to full-time braces.

With help of an innovative MRI technique, so called BoneMRI (BoneMRI, MRIGuidance, Utrecht, the Netherlands), it is now possible to capture both, bony structures and soft tissues, in detail within one imaging modality. Both structures are involved in the onset and development of this common deformity. This new MRI technique is built by an algorithm based on a Convolutional Neural Network (CNN) which permits to develop a high quality synthetic CT (sCT), providing great bony detail as well as the well-known quality of soft tissue imaging, without harmful radiation.

Study objective

To quantify how much a full-time brace corrects the spine in 3D in AIS patients when supine, compared to a dedicated night-time brace.

Study design

prospective multicentre observational cohort study

Study burden and risks

These patients will undergo brace treatment and follow-ups according to standard clinical care. The inclusion criteria are generally accepted criteria for AIS brace treatment. Standard care includes a full-spine radiograph before brace treatment, after the patients gets used to wearing the brace (to check for in-brace correction) and at 6-monthly follow-ups. In between brace measurement and delivery of the brace to the patient, it normally takes 3-4 weeks.
This study can only be done within these subject groups, because scoliosis-braces are only used in this population. These scans are important to

understand how the brace treatment corrects the 3D shape of the spine in its bony structures as well as the intervertebral disc (IVD). Obviously, ionizing radiation should be avoided thus the choice for MRI. The duration of the MR imaging in this study is minimized (shortened from 45 to 20 minutes) contrast or sedation are not needed. According to the *Toetsing van onderzoek met minderjarige proefpersonen* of the CCMO, MRI (without sedation and contrast) are research procedures with minimal risk and burden.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

1. Females

2. 10-18 years of age
3. Diagnosis of AIS
4. 20-40° of coronal Cobb angle
5. No previous scoliotic brace or surgical treatment
6. Risser 0-2
7. pre-menarche or max 1-year post-menarche
8. Prescription of one of the following braces: Providence (night-time, UMCU), Chenau-type (full-time, Erasmus MC)
9. Written informed consent

Exclusion criteria

1. Any additional spine pathology
2. Non-idiopathic scoliosis (e.g. Syndromes associated with growth disorders, neuromuscular or connective tissue disorders)
3. contra-indication for MRI: vascular clips (absolute contra-indication), pacemaker and defibrillators (relative contra-indications), prostheses and other metal objects (due to risk of artifacts)
4. Claustrophobia

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-08-2024
Enrollment:	40
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	15-03-2024
Application type:	First submission
Review commission:	METC NedMec

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	NL84234.041.24