Assesment of the stiffness of the trunk by the Scolibed

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Determine the repeatability, inter and intra-observer variability of the *Scolibed*. Determine the variation in stiffness for healthy individuals and for scoliotic patients. Compare the results of healthy individuals and scoliotic patients.

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

Summary

ID

NL-OMON41484

Source
ToetsingOnline

Brief title
Scolibed: Assessment of Truncal Stiffness

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Bone and joint therapeutic procedures

Synonym
Scoliosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Assessment, Device, Spine, Stiffness

Outcome measures

Primary outcome

Determine the repeatability, inter and intraobserver variability of the

Scolibed.

Secondary outcome

Determine and compare the stiffness and the variation in stiffness of the trunk

of scoliotic patients and healthy individuals.

Study description

Background summary

Scoliosis is a progressive spinal deformation. A new system was developed to correct scoliosis without the up-to-now inevitable fusion of the spine, resulting in a completely stiff spine. This non-fusion scoliosis correction system corrects the spine and keeps it flexible. Since the spine is connected to the trunk, the trunk is corrected as well.
To determine the optimal correction capacity of this scoliosis correction device it is necessary to determine the individual stiffness of the patient*s trunk. To determine the stiffness of the trunk, a device named *Scolibed* was developed. It is a bed-shaped mechanical system, divided into a lower and upper part, connected by an axis. By placing the patient on his back on the table, both lateral bending and torsional stiffness can be measured. By placing the patient on his side, flexion and extension stiffness can be measured.
It is unknown whether the device can measure the stiffness in a reproducible way and whether there is a large individual variation. From a scientific point of view it is interesting to know if the stiffness of a scoliotic spine is different from a healthy one, since it may provide information about the underlying mechanisms of scoliosis, which are unknown up to now.
The first phase of the study is a pilot study to assess the reproducibility of the device to observe and compare the variation in stiffness found among healthy subjects and scoliotic patients. The results of the first phase will be used as the basis for the second phase, a case-control study assessing truncal

stiffness in healthy subjects and patients.

Study objective

Determine the repeatability, inter and intra-observer variability of the *Scolibed*. Determine the variation in stiffness for healthy individuals and for scoliotic patients. Compare the results of healthy individuals and scoliotic patients.

Study design

Interventional pilot study

Design
Interventional pilot study. First phase directed to determine if the device is reliable and accurate. Second phase is going to be performed to assess the difference in truncal stiffness between healthy subjects and scoliotic patients.

Duration
First phase: From October 2014 until July 2015.
Second phase: Six to eight months, the starting date depends on the results of first phase.

Setting
First phase: 15 healthy volunteers to be recruited in Groningen.
15 volunteer scoliotic patients are to be recruited among the patients in treatment at University Medical Center Groningen (UMCG) by the orthopaedic surgeons working at the hospital. All measurtements are performes at the UMCG, dept of Orthopedics.
If a subject shows interest, he or she will be given an Inform Consent Letter to be signed.

Intervention

Stiffness of the trunk will be measured.

Study burden and risks

The subjects are positioned on a vacuum mattress that is fixed to the *Scolibed* and strapped to the bed with Velcro® straps that are passed over the subject*s body (two straps over the upper part and three straps over the pelvis and legs). Then the upper part is rotated relatively to the lower part.
The burden for the subjects are the tightness of the straps, and the unnatural feeling of being bent. The maximum time for a measurement session is limited to 60 minutes and will be done after a regular appointment with the orthopedic surgeon in case of patient subjects. Four measurement sessions have to be

performed, three in the same day and one with a time difference of minimum 5 days and maximum 20 days.
The main risk is that the subject is bent too much and will experience pain. But since this bending is done manually, an immediate stop and movement back is possible. Other risks are:
• Fracture of the upper and/or lower part of the device and failure of the fixation of the vacuum mattress to the bed or of the straps, both resulting in a fall of the subject on the ground. The system has been designed for subjects of 120 kg with a safety factor of 1,5. The design has been tested with this load and passed without any signs of failure.
• Electric hazard. The resulting rotation is measured electronically and thus there is a risk for an electric shock. This risk is very low, since the patient is lying on a polymer mattress and a wooden bed frame. Moreover, the sensors are running on low voltage.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)

Inclusion criteria

Control group:;- Age between 12 and 14 years old
- Individuals able to walk and perform all trunk movements
- Weight < 120 kg;Study group:
- Idiopathic or congenital scoliosis
- Age between 12 and 14 years old
- Under treatment at scoliosis clinic in UMCG
- Capability to stand up normally without any supporting devices
- Range of Cobb angle: between 20° and 60 °
- Weight < 120 kg;Het subject moet voorafgaand aan deelname het 'written' informed consent tekenen, dat bijgeleverd wordt aan dit formulier.

Exclusion criteria

Control group:;- Pregnancy
- Already accomplished significant spinal surgery
- Recent surgery in trunk or abdomen. Use of implants or prosthesis in trunk or abdomen which limits body motion.
- Back pain
- Neurological disorder
- Any spinal disease
- Body malformation with effects on body motion
- History of spinal injury and/or ribcage injury
- History of handicap
- Use of strong painkillers or opioids;Study group:;- Pregnancy
- Already accomplished significant spinal surgery
- Back pain
- Neurological disorder
- Spinal disease not related to scoliosis
- Body deformation unrelated to scoliosis
- Scoliosis with Cobb*s Angle <20º or >60º
- Use of strong painkillers or opioids

Study design

Design

Study type:	Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Scolibed
Registration:	No

Ethics review

Approved WMO

Date:	29-07-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ISRCTN	ISRCTN63196384
CCMO	NL47170.042.15