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The assessment of the stiffness of the trunk by the Scolibed

Submission date
24/03/2015

Recruitment status
No longer recruiting

Registration date
06/05/2015

Overall study status
Completed

Last Edited
14/08/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Scoliosis is a progressive condition where the spine twists and curves in an abnormal way over time. Symptoms include a curved spine, prominent ribcage and one shoulder being higher than the other. It can cause back pain, particularly in adults, emotional problems (associated with body image and self-esteem) and, in some more severe cases, lung and heart problems as the ribcage can be pushed against these organs. In some cases, again particularly in adults, the bones in the spine can compress nerves which can lead to a number of problems including back and leg pain, numbness in the legs, incontinence and (in men) erectile dysfunction. One possible treatment is surgery, where the spine is moved to a more normal position using metal rods, plates and screws before finally being fused into place with bone grafts. This results in a completely stiff spine. A new system has been developed which corrects the spine which fusion, keeping it flexible. Since the spine is connected to the trunk (torso), this is corrected as well. To assess the new 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" has been developed. It is a bed-shaped mechanical system, divided into two parts, connected by an axis. 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 not currently known. Here, we aim to the reproducibility of the device to observe and compare the variation in stiffness found among healthy subjects and scoliotic patients. The results of this work will be used as the basis for a bigger study assessing truncal stiffness in healthy subjects and patients.

Who can participate?
Healthy volunteers, between 12 and 14 years old and scoliotic patients, between 12 and 14 years old.

What does the study involve?
The participants 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 legs). Then the upper part is rotated relative to the lower part.

The burden for the subjects is 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. In this way, we hope to determine the repeatability of the “Scolibed” results, variation in stiffness for healthy individuals and variation in stiffness for scoliotic patients. We will also compare the results of healthy individuals and scoliotic patients.

What are the possible benefits and risks of participating?
The main risk of taking part in the study is that the participant is bent too much and experience pain. But since this being is done manually an immediate stop and movement back is possible. There is also a risk of device breaking or malfunctioning, causing the participant to fall on the ground. The design has been tested with volunteers and passed without any signs of failure. Finally, it is possible that the participants will receive an electric shock from the device. This risk is very low, however, since the patient is lying on a plastic vacuum mattress and a wooden bed frame and the sensors are running on low voltage.

Where is the study run from?
Department of Orthopaedic Surgery, Groningen University Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
April 2015 to May 2015

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Professor Bart Verkerke

Contact information

Type(s)
Scientific

Contact name
Dr Bart Verkerke

Contact details
Postbus 196
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The assessment of the stiffness of the trunk by the Scolibed: a pilot study

Study objectives
1. The expectation of the first phase is that the device will be reproducible.
2. The expectation of the second phase is that the range of truncal stiffness of healthy individuals and scoliotic patients measured by the device will be small.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nit provided at time of registration

Study design
Interventional 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.

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Scoliosis

Interventions
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 legs). Then the upper part is rotated relative to the lower part.

Intervention Type
Device

Primary outcome measure
1. Our first goal is to determine the device's reproducibility. To assess the influence of time variation and operator variation and also to determine the repeatability, each subject must undergo four series of measurements, three in one day (day one) and one after minimum five days and maximum 20 days (day two).
2. After organizing the results a simple analysis regarding the difference among the intra-subject results will be performed using the statistics software SPSS. With the outcome of this analysis, each subject will have a number (referent to the difference found among the results). We will call this number "Variation Coefficient", shortly "VC", and like in the table above, we will work with "S1VC", "S2VC", and so on. It is determined by calculating the ratio of the standard deviation to the mean value of the intra-subject results. The same statistical method is going to be used to analyse the inter-subject results.

Secondary outcome measures
Range of truncal stiffness of healthy individuals and scoliotic patients measured by "Scolibed". We intend to perform statistical analysis of variation to determine if the difference on the stiffness found between our control and study group is statistically significant. After ensuring that the difference found is not "by accident" we want to add some variants (such as gender and severeness of the curve) and compare the results and the likelihood of some statements according to the data collected (e.g. How likely it is that truncal stiffness is larger/ lower in scoliotic patients than in healthy subjects.).

Overall study start date
07/04/2015

Completion date
01/06/2015

Eligibility

Key inclusion criteria
Control group:
1. Age between 12 and 14 years
2. Individuals able to walk and perform all trunk movements
3. Weight < 120 kg

Study group:
1. Idiopathic or congenital scoliosis
2. Age between 12 and 14 years
3. Under treatment at the scoliosis clinic in the UMCG
4. Capability to stand up normally without any supporting devices
5. Cobb angle: between 20° and 60 °
6. Weight < 120 kg

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit

12 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
Control group:
1. Pregnancy
2. Already underwent spinal surgery
3. Recent surgery in trunk or abdomen. Use of implants or prosthesis in trunk or abdomen which limits body motion.
4. Back pain
5. Neurological disorder
6. Any spinal disease
7. Body malformation with effects on body motion
8. History of spinal injury and/or ribcage injury
9. History of handicap
10. Use of strong painkillers or opioids

Study group:
1. Pregnancy
2. Already underwent spinal surgery
3. Back pain
4. Neurological disorder
5. Spinal disease not related to scoliosis
6. Body deformation unrelated to scoliosis
7. Scoliosis with Cobb's Angle <20° or >60°
8. Use of strong painkillers or opioids

Date of first enrolment
07/04/2015

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Orthopaedic Surgery, Groningen University Medical Centre (Universitair Medisch Centrum)

Netherlands
9700 RB

Sponsor information

Organisation
Faculty of Medical Sciences / UMCG, Orthopedics (Faculteit Medische Wetenschappen/UMCG, Orthopedie)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/012p63287

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request