ISRCTN63278972 https://doi.org/10.1186/ISRCTN63278972

Trunk muscle strength and limitations in functioning in children and youth with spinal muscular atrophy

Submission date
04/04/2017

Recruitment status
No longer recruiting

Registration date
11/04/2017

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Spinal muscular atrophy (SMA) is a rare inherited condition that causes muscle weakness and progressive (worsening over time) loss of movement. It is caused by deterioration in the nerve cells connecting the brain and spinal cord to the body's muscles. As the link between the nerves and muscles breaks down, patients gradually lose their ability to move and their muscles waste away (atrophy). The aim of this study is to assess the strength of muscles in the trunk (torso) for rotational activity (twisting) and the level of independent functioning in children and youth with SMA.

Who can participate?
Patients aged 5-18 years who have been diagnosed with SMA and helathy children and youths of the same age.

What does the study involve?
All participants attend a single study visit at which the strength of their trunk (torso) is measured using a handheld measurement device while they are lying on their side. This is done at six points on the body. Following this, participants are asked to complete questionnaires about their daily activities and any limitations they may be facing as well as background information.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
Center of Functional Rehabilitation ORTHOS (Poland)

When is the study starting and how long is it expected to run for?
December 2016 to December 2017

Who is funding the study?
Józef Piłsudski University of Physical Education (Poland)

Who is the main contact?
Dr Agnieszka Stępień

Contact information

Type(s)
Scientific

Contact name
Dr Agnieszka Stępień

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1/2017

Study information

Scientific Title
Strength of trunk rotational muscles and limitations in everyday functioning in children and youth with spinal muscular atrophy

Acronym
SMA

Study objectives
1. Strength of trunk muscles responsible for rotating trunk or pelvis in SMA children and youth is lower than in healthy peers
2. There is a correlation between the strength values of these muscles and limitations in everyday functioning

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Senate Research Ethics Committee at Józef Piłsudski University of Physical Education in Warsaw, Poland, 07/02/2017, ref: SKE 01-03/2017

Study design
Single-centre case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Spinal muscular atrophy

Interventions
All participants will have a one-time measurement of muscle strength taken in a side-lying position using a handheld MICROFET measurement system. The device will be placed consecutively in three points on the front side of the body (i.e. forehead; trunk – in the shoulder joint area; trunk – in the anterior superior iliac spine area) and later in three points at the back of the body (i.e. posterior middle part of the skull; posterior part of the trunk in the shoulder joint area; pelvis – below iliac crest). 5-10 seconds will be devoted to one measurement during maximal isometric tension. Two series of measurements on each side will be performed in each of the aforementioned points. A higher value will be included in the analysis.

Participants will be also asked to complete a questionnaire including questions regarding limitations during everyday activities. Additional information will be collected on age, gender, accompanying illnesses.

Intervention Type
Other

Primary outcome measure
1. Strength of muscles responsible for trunk rotation is assessed using a handheld MICROFET, in which the value of strength expressed in pounds or Newtons in a pre-set time unit, on the study visit

2. Functioning limitations are measured using a questionnaire designed for the purpose of this study, including questions regarding limitations during everyday activities prepared on the basis of ICF on the study visit

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/2016

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Patients:
1. Spinal muscular atrophy (SMA) diagnosed through clinical and genetic examinations
2. Aged 5-18 years

Controls:
1. Healthy
2. Aged 5-18 years
3. Do not practice sport

Participant type(s)
Mixed

Age group
Child

Lower age limit
5 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
minimum 30

Total final enrolment
56

Key exclusion criteria

Patients:
1. No confirmation of SMA in genetic tests
2. Children under 5
3. Children and youth not able to cooperate during an examination

Controls:
1. Age under 5 or over 18
2. Children not able to cooperate during an examination.

Date of first enrolment
15/04/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Poland

Study participating centre
Center of Functional Rehabilitation ORTHOS
Modzelewskiego 37
Warsaw
Poland
02-679

Sponsor information

Organisation
Józef Piłsudski University of Physical Education

Sponsor details
Marymoncka 34
Warsaw
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Sponsor type
University/education

ROR
https://ror.org/043k6re07

Funder(s)

Funder type
University/education

Funder Name
Józef Piłsudski University of Physical Education

Results and Publications

Publication and dissemination plan
The results will be published in an article in a neurologic, physical therapy or rehabilitation journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Agnieszka Stępień (orthosas@wp.pl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/04/2021	07/06/2023	Yes	No