Measuring physical capacity, musculoskeletal complaints, and physical and psychosocial functioning in children and adolescents with connective tissue disorders.

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To objectively determine the severity of CTD related physical impairments, complaints and difficulties during participation in daily life activities. An additional study objective is: - To determine risk factors for the development of health...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON49435

Source
ToetsingOnline

Brief title
Follow You measurement

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
connective tissue disorder, hyperextensibility of joints

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: SIA RAAK PRO

Intervention

Keyword: Children, Complaints, Connective tissue disorder, Screening

Outcome measures

Primary outcome

This study will assess musculoskeletal complaints (pain, flexibility), physical

capacity (cardiorespiratory endurance and muscle strength), physical

performance (motor performance, activity level).

Secondary outcome

Intelligence, psychological and social functioning.

Study description

Background summary

A connective tissue disorder (CTD) is group-name for diseases that are generally characterized by systemic problems affecting cardiovascular, muscular, and pulmonary systems, as well as joint hypermobility, skin hyper extensibility, and tissue fragility. Three well-known types of CTD*s are Ehlers-Danlos Syndromes (EDS), Marfan syndrome (MFS) and Loeys-Dietz syndrome (LDS). The incidence is low, approximately 1-3 per 10,000 children will be diagnosed with a CTD.

Health problems related to the disease can be diverse and have major consequences for physical, social and psychosocial functioning and the health-related quality of life. Hypermobility of joints in children will often result in injuries and pain. This can lead to lower physical activity, increased absenteeism and reduced physical and psychosocial functioning. Together, the disease has a major impact on the life of the child and his family. That is why specialist care and supervision are necessary. At five locations in the Netherlands, including the Amsterdam UMC, location AMC, there are specialist teams that take care of children, adolescents and adults with

MFS and LDS. But current monitoring and supervision focuses primarily on the direct disease effects (eye and heart) and possibly are not sufficient enough on more indirect effects.

In a previously performed survey among a large group of children with CTD, the impact of the disease was investigated in an online survey. Data on physical and psychosocial complaints and functioning, as well as family functioning and health-care use were analyzed per disease group, age and gender. From the results we selected important topics to be included in a new, smart developed, test battery to assess musculoskeletal complaints, physical capacity and physical performance as well as physical and psychosocial functioning.

Study objective

To objectively determine the severity of CTD related physical impairments, complaints and difficulties during participation in daily life activities. An additional study objective is:
- To determine risk factors for the development of health problems and severity of complaints

Study design

This study is a prospective observational study, with a nine-month follow-up. In total, 75 to 100 Dutch, and 50 Belgium children with CTD will be included in de study. Children will be assessed on their musculoskeletal complaints, physical capacity and physical performance as well as psychological and social functioning.

Study burden and risks

There will be a low risk for study related burden. The impact of the physical tests can be compared with a general gym class at school.
Screening results might indicate need for additonal health care; when needed and wanted children will be refered to pediatric specialist. In addition, for each participant, future benefits after improvement of CTD complain screening and delivered healthcare is possible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

This study will include children and adolescents (4-18 years old) who are diagnosed with either Marfan syndrome, Ehlers-Danlos Syndromes or Loeys-Dietz syndrome. In the Netherlands, children need to be treated in the Amsterdam University Medical Centers (UMC), location AMC, or in another hospital when the children are diagnosed with Ehlers-Danlos.
In Belgium, children need to be treated in the University Hospital Ghent (UZ-Ghent).
The origin of the children and parents can be of every country and/or ethnicity.

Exclusion criteria

Children/ adolescents who, next to the Marfan syndrome, Ehlers-Danlos Syndromes or Loeys-Dietz syndrome, have another prominent chronic disease affecting their physical functioning, or children who are seriously cognitive impaired or completely wheelchair dependent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	05-02-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL69650.018.19

Study results

Date completed: 24-02-2021

Actual enrolment: 42

Summary results
Trial is onging in other countries