Musculoskeletal pain in adolescents with Generalized Joint Hypermobility in the context of activity impairment

Published: 15-06-2015
Last updated: 15-04-2024

To determine the contribution of musculoskeletal pain to activity limitations corrected for the impact biomechanical factors (joint biomechanics, proprioception, physical fitness) and psychological comorbidity. The secondary objective is to identify…

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

Summary

ID

NL-OMON46951

Source
ToetsingOnline

Brief title
Musculoskeletal pain and Generalized Joint Hypermobility

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
Ehlers-Danlos (hypermobility type), Hypermobility Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,NWO: promotie beurs voor leraren

Intervention

Keyword: Gait analysis, Generalized joint hypermobility, Hypermobility Syndrome, Musculoskeletal pain

Outcome measures

Primary outcome

The primary outcomes will be set at the amount of activity impairment.

Secondary outcome

Secondary outcomes will entail potential contributing factors for activity

impairment in terms of Musculoskeletal complaints (pain and fatigue), physical

factors (Joint biomechanics, muscle power, proprioception) and psychological

factors (psychological comorbidity and parental factors).

Study description

Background summary

Musculoskeletal pain is the primary feature of children diagnosed with Hypermobility Syndrome (HMS) and Ehlers Danlos hypermobility type (EDS-HT). In addition a high prevalence of (chronic) fatigue, psychological distress and deconditioning have been reported in literature. As a result these children are often mild to severely impaired in activities, leading to chronic disability and social restrictions in early childhood to even more extensively in later stages of life. The most striking clinical characteristic of HMS/EDS-HT is the presence of an excessive range of joint motion, also known as Generalized Joint Hypermobility (GJH), which is hypothesized to be causative for the development of musculoskeletal pain and functional decline. However GJH is also common within normal child populations and only 1% to 3% will develop HMS/EDS-HT, and musculoskeletal pain is only episodically and does not become chronic. Till present day no pathophysiological has been identified as well as factors that may underlie functional decline.

Study objective

To determine the contribution of musculoskeletal pain to activity limitations corrected for the impact biomechanical factors (joint biomechanics,

proprioception, physical fitness) and psychological comorbidity. The secondary objective is to identify discriminative factors between children with HMS/EDS-HT and GJH in order to develop patient risk profiles for HMS/EDS-HT.

Study design

The study has a cross-sectional design. A multi-level factorial analysis will be performed, according to mixed linear models, on the association of activity impairments with Musculoskeletal pain. Due to the number of included outcomes data reduction will be performed by discriminative analysis. Factors that are discriminative between groups (healthy controls without GJH, healthy children with GJH and HMS/EDS-HT) will form the basis of the associative models, in order to determine the relevance of these factors to activity impairment.

Study burden and risks

The participants are required to one visit to the rehabilitation department of the AMC. All procedures are part of the clinical routine and have been found safe. However the measurements can be exhausting and the questions in the questionnaire can concern intimate information.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9 Meibergdreef 9
Amsterdam 1105 Az
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9 Meibergdreef 9
Amsterdam 1105 Az
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion will be based on one of the following diagnoses:;Hypermobility Syndrome: according to the Brighton criteria
Ehlers Danlos (hypermobility type): Villefranche criteria
Generalized Joint Hypermobility: Beighton score >4

Exclusion criteria

Primary exclusion criteria encompass the presence of other heritable disorders of connective tissue (HDCT) like Ehlers-Danlos (other than the hypermobile type), Marfan syndrome or osteogenesis imperfecta. If genetic screening rules out HDCT*s, the participant is again eligible for inclusion in the study.;Secondary exclusion criteria encompass:
-A history of surgery is present on the extremities, spine or thorax that could interfere with walking, or with arm/hand function related activities.
-Any conditions that render the participant too unfit to be tested (such as pulmonary and/or cardiac disorders)
-Any conditions that render the participant unable to understand or adhere to the protocol (such as cognitive, social, visual and/or language problems, or hand problems, that render the patient unfit to fill-in the questionnaires).

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:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2016
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	15-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	15-06-2016
Application type:	Amendment
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	NL51223.018.15