Compromised mandibular function in Juvenile Idiopathic Arthritis: the silent temporomandibular joint paradigm

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48942

Source
ToetsingOnline

Brief title
JIA and the silent TMJ

Condition

- Autoimmune disorders

Synonym
Juvenile Idiopathic Arthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bite Force, Juvenile Idiopathic Arthritis, Magnetic Resonance Imaging, Temporomandibular Joint

Outcome measures

Primary outcome

MRI, bite force

Secondary outcome

Physical examination TMJ and Questionnaire

Study description

Background summary

Juvenile idiopathic arthritis (JIA) is the most common rheumatic disease in children. According to the ILAR classification, JIA is diagnosed when the complaints have been present over six weeks, with an onset before the age of sixteen. Early detection and management of temporomandibular joint (TMJ) involvement of JIA prevents the sequels of the disease in the masticatory system such as pain, reduced mouth opening, dysfunction of joints and muscles, and growth disturbances leading to facial and mandibular deformities. Screening by the rheumatologist can detect TMJ involvement but clinical assessments only such as pain assessment and measuring mandibular range of motion have a high specificity but low sensitivity. This may have to do with the silent joint paradigm: children diagnosed with JIA and TMJ arthritis confirmed by MRI, being the gold standard, may lack clinical signs or symptoms. This hampers early detection of TMJ arthritis, resulting in treatment delay.

Study objective

The objective of our study is i) to verify the *silent* joint paradigm: to assess the TMJ using MR imaging in children with new onset not yet treated JIA, without clinical signs and symptoms indicating TMJ arthritis; ii) to assess the utility of bite force measurement as predictor for TMJ arthritis.

Study design

cross-sectional study

Study burden and risks

The results of this study are expected to contribute to a better understanding of detection TMJ involvement in children with new onset JIA as well as in children in regular treatment. The burden of participation in our study consists of I) taking the decision to participate in our study, II) one MRI, III) measurement of the bite force, IV) clinical TMJ examination, V) filling out one questionnaire, VI) measuring the maximum mouth opening at home and VII) chewing on a wax tablet (to measure the masticatory performance). The need for MRI may decrease if bite force turns out to be a valid predictor of TMJ inflammation.

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

o Score *0* points on the TMJ screening protocol
o Not yet in regular care for JIA by the rheumatologist (new onset JIA) or diagnosed JIA with an exacerbation and not yet started adequate therapy.
o Age * 6 years; < 16 years of age at JIA diagnosis
o Given oral and written informed consent

Exclusion criteria

o Received previous TMJ treatment
o Undergoing orthodontic treatment
o History of mandibular trauma
o Contra-indication for MRI
o Need for sedation prior to MRI e.g. as a result from claustrophobia

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):	28-05-2018
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	Bite Force Transducer
Registration:	No

Ethics review

Approved WMO Date:	21-12-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-02-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL62448.041.17