A pilot study on magnetic resonance imaging of the distal radial growth plate: defining healthy and pathologic characteristics in a non-invasive manner

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON43849

Source
ToetsingOnline

Brief title
Physeal MRI Pilot

Condition

- Bone disorders (excl congenital and fractures)

Synonym
gymnast wrist, radial epiphysitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gymnastics, MRI, Physis, Radius

Outcome measures

Primary outcome

Early signs of growth plate injury on conventional radiographs, standard MRI sequences and on MRI sequences sensitive for cartilage imaging, such as oedema, bony bridges and growth plate widening;

Secondary outcome

- Skeletal age as determined from a hand radiograph;
- Signs of distal radial growth plate injury on hand radiographs, such as widening and haziness of the growth plate;
- Quantification of growth plate pathology on DWI MR images using ADC maps;
- Growth plate volume derived from 3D mapping;
- Growth plate thickness;
- Clinical signs and severity of distal radial growth plate injury such as wrist pain;
- Anthropomorphic characteristics (length, weight) and training characteristics (starting age, level, training intensity in hours, training frequency in days, specialty elements) of participants.

Study description

Background summary

Chronic wrist pain is an overuse syndrome frequently affecting young gymnasts, and often involving the radial growth plate. In the immature skeletal system, growth plates are potential sites of injury due to chronic repetitive axial loading of the wrist joint. Such injury can lead to growth abnormalities at a later age. In the athlete with chronic wrist pain, imaging of the wrist is thus essential for early diagnosis and to visualize possible degenerative changes of the wrist. Early diagnosis leading to appropriate treatment can aid in preventing worse outcome on the long term. At present, general consensus on optimal magnetic resonance imaging (MRI) of the growth plate does not exist. We hypothesize that MRI is useful for clear visualization of the growth plate and for detecting early signs of growth plate injury.

Study objective

1. The primary objective is to evaluate the characteristics of the distal radial growth plate on MRI (including functional imaging techniques) and on conventional radiographs in young gymnasts with wrist pain, compared to young gymnasts without wrist pain and to young non-gymnasts.

2. The secondary objectives are:
- To evaluate the additional value of MRI over conventional radiography in the evaluation of distal radial growth plate injuries;
- To evaluate the role of additional MRI applications (DWI MRI, 3D physeal mapping) in quantifying and staging radial growth plate pathology;
- To correlate anthropomorphic and training characteristics as well as clinical signs of wrist overuse injury with the characteristics of the distal radial growth plate on imaging in young symptomatic and asymptomatic gymnasts and non-gymnast controls;
- To compare bone age with characteristics of the distal radial growth plate on MRI in gymnasts and non-gymnast controls;
- To develop an optimal MRI protocol (including functional imaging techniques) for the diagnosis and staging of distal radial growth plate injuries, to be used in clinical practice, in patients with suspected injury of the distal radial growth plate.

Study design

Prospective observational study. We will obtain PA radiographs and MR images of the wrist in a small group of young gymnasts with wrist pain, in a group of young gymnasts without wrist pain, and in a control group of young non-gymnasts. Wrist radiographs will be used for screening for distal radial growth plate pathology and for assessment of bone age using automated software (BoneXpert). MR images will be interpreted by an experienced musculoskeletal radiologist and an experienced musculoskeletal radiology resident. All images will be compared between gymnasts with wrist pain, gymnasts without wrist pain, and non-gymnast volunteers to assess anatomic aspects and to identify signs of

distal radial growth plate injury.

Study burden and risks

Gymnasts with wrist pain, gymnasts without wrist pain and non-gymnasts are asked to participate in this study.
1. All participants will have to travel to the AMC in order to undergo imaging;
2. Participants will be asked to fill out a short questionnaire on wrist pain and gymnastics or other sports performance (additional examination time: 5 minutes);
3. Participants will undergo physical examination of the wrist (additional examination time: + 5 minutes);
5. All participants will undergo MRI scanning of the wrist (scan time: 45 minutes).
6. All participants will undergo a single wrist radiograph (radiation exposure: 0.001 mSv).

Gymnasts with wrist pain may benefit when early signs of wrist overuse injury are identified during this study and adequate treatment can be initiated at an early stage. For the purpose of studying the active growth plate, inclusion of a patient group younger than 18 years is unavoidable.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

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

Symptomatic gymnast group:
- Age range 12-18 years;
- Open radial growth plate on hand radiograph;
- Gymnastics participation in six months before inclusion, for duration a period of at least one year and up to six months or less before moment of inclusion in the study;
- Wrist pain in past 6 months;
- Written informed consent by participant;
- Written parental consent.;Asymptomatic gymnast group:
- Age range 12-18 years;
- Open radial growth plate on hand radiograph;
- Gymnastics participation for a period of at least one year and up to six months or less before moment of inclusion in the study;
- No wrist pain in past 6 months;
- Written informed consent by participant;
- Written parental consent.;Non-gymnast control group:
- Age range 12-18 years;
- Open radial growth plate on hand radiograph;
- No gymnastic participation at present or in the past;
- No participation of other wrist-loading sport with risk of wrist overuse injury (i.e. racquet sports, volleyball, field hockey, rowing, judo) for more than twice a week;
- No history of wrist trauma, such as wrist fracture;
- Written informed consent by participant;
- Written parental consent.

Exclusion criteria

- History of past fracture, infection or surgery of the wrist;
- Diagnosed with any growth disorder;
- Diagnosed with systemic disease involving the musculoskeletal system (e.g. juvenile idiopathic arthritis);
- Oncological disease involving the musculoskeletal system;
- Fully closed growth plate on wrist radiographs, indicative of skeletal maturation;
- No written informed consent.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2015
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-02-2016
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	NL51814.018.14

Study results

Date completed: 12-11-2018

Actual enrolment: 69

Summary results
Trial ended prematurely