The value of ultrasound compared to magnetic resonance imaging in haemophilic arthropathy

Published: 14-08-2014
Last updated: 21-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON40804

Source
ToetsingOnline

Brief title
US versus MRI in haemophilic arthropathy

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Blood and lymphatic system disorders congenital

Synonym
Haemophilic arthropathy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Arthropathy, Haemophilia, MRI, Ultrasound

Outcome measures

Primary outcome

Research question 1: Ultrasound and MRI scores for synovial hypertrophy according to the HEAD-US score and the additive IPSG MRI score respectively.

Secondary outcome

Research question 2a: MRI scores for synovial hypertrophy, haemosiderin, and osteochondral defects on the initial MRI, and MRI scores for osteochondral defects at re-examination.

Research question 2b: MRI scores for synovial hypertrophy at the initial MRI, and MRI scores for synovial hypertrophy at re-examination.

Determinants of interest are: Number of joint bleeds between MRI examinations specified per joint, age, history of joint injuries, and Body Mass Index (BMI).

Study description

Background summary

Repeated provoked or spontaneous bleeding into the joints are the hallmark of haemophilia. Recurrent or prolonged joint bleeds eventually lead to synovial hypertrophy, progressive cartilage degradation and bone damage through mechanical and metabolic joint destruction. Joint assessment in haemophilia is important to assess results of the expensive replacement therapy with clotting factor concentrates. Traditionally, the six main joints (elbows, knees, and ankles) were examined with standard X-rays. However, standard X-rays are able to assess osteochondral changes only, and therefore detect late and mostly irreversible joint changes. From a clinical perspective, it is important to assess early, potentially reversible, joint changes in patients with normal findings on physical examination and X-ray. Consequently there is an increasing interest in the use of Magnetic Resonance Imaging (MRI) and ultrasound. MRI is

the most sensitive imaging modality to demonstrate effusion or haemartrosis, synovitis, and cartilage defects. However, MRI assessment is less available than a standard X-ray, it is expensive and time consuming. Therefore MRI is not the first choice for routine joint assessment in the absence of major complaints. The typical haemophilic joint changes including effusion or haemartrosis, synovitis, and cartilage defects can be assessed by ultrasound too and show strong correlations with MRI findings. Unfortunately the operator dependency of ultrasound is a potential disadvantage, and previous ultrasound protocols for haemophilic arthopathy were too time consuming to use in daily practice. For both imaging modalities new scoring systems have been published recently to evaluate haemophilic arthropathy: the MRI scale by the International Prophylaxis Study Group (IPSG) and a simplified ultrasound scanning procedure (Haemophilia Early Arthropathy Detection with Ultrasound (HEAD-US)). So far, there is no literature available about the accuracy of the HEAD-US score compared to MRI. The clinical relevance of early changes detected by MRI and ultrasound is still unclear. It is not known if subtle alterations such as haemosiderin and synovial hypertrophy seen on MRI are reversible or not, and if they have a predictive value for development of osteochondral changes.

Study objective

The primary objective of this study is to establish the diagnostic accuracy of ultrasound assessment of the synovium in haemophilic arthropathy compared to MRI. Secondary objectives are (2A) to determine whether or not synovial hypertrophy on MRI is able to predict osteochondral changes on MRI five years later and (2B) to evaluate if intra-articular haemosiderin be cleared in five years.

Study design

Cross-sectional study for the primary objective on the value of ultrasound in patients with haemophilia. Longitudinal observational study for the secondary objectives using clinical follow-up and baseline data of a previous MRI study (METC 07-220).

Study burden and risks

Participating patients will spent more time in the hospital at the day of their planned clinical follow-up due to the additional US and MRI examination. Patients will not have a direct benefit from participating in this study: their bleeding pattern and current outcome will not change. On long term, patients are expected to benefit from the optimization of treatment due to detailed assessment of outcome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Clinical and radiological absent or minimal arthropathy
• Participation in MRI study by Den Uijl:
- MRI assessment of both knees and ankles by the standardized MRI protocol described by Den Uijl in 2009/2010
- Severe (<1% FVIII/IX activity) or moderate haemophilia (1-5% FVIII/IX activity)

Exclusion criteria

• History of inhibitors
• Contra indication for MRI
• Exclusion of joints in case of a severe joint injury, joint surgery, or development of a target

joint since initial MRI assessment in 2009/2010

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2014
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO

Date:	14-08-2014
Application type:	First submission
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	NL49256.041.14