

De waarde van echo en MRI bij de evaluatie van gewrichtsschade bij hemofilie

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24318

Source

Nationaal Trial Register

Health condition

haemophilia, arthropathy, joint damage

Sponsors and support

Primary sponsor: University Medical Center Utrecht

Source(s) of monetary or material Support: Unrestricted research grant by Baxter

Intervention

Outcome measures

Primary outcome

Diagnostic accuracy of ultrasound assessment of the synovium in haemophilic arthropathy compared to MRI

Secondary outcome

* Association of soft tissue changes on initial MRI with osteochondral changes on re-

examination after 5 years

* Reversibility of intra-articular haemosiderin

Study description

Background summary

Repeated provoked or spontaneous bleeding into the joints are the hallmark of haemophilia. From a clinical perspective, it is important to assess early, potentially reversible, joint changes in patients with normal findings on physical examination and X-rays. Consequently there is an increasing interest in the use of Magnetic Resonance Imaging (MRI) and ultrasound. So far, there is no literature available about the diagnostic accuracy of a recently developed, simple and fast, ultrasound protocol. Besides, 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.

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 to determine whether or not synovial hypertrophy on MRI is able to predict osteochondral changes on MRI five years later and to evaluate if intra-articular haemosiderin can be cleared in five years.

Study objective

- The diagnostic accuracy of ultrasound assessment regarding the synovium in patients with haemophilia is > 70%.
- Soft tissue changes on initial MRI are associated with osteochondral changes on re-examination after 5 years, independent of bleeding-history in patients with haemophilia.
- Haemosiderin on MRI could be cleared five years later in joints of haemophilic patients without new joint bleeds

Study design

-

Intervention

Diagnostic procedures:

* Ultrasound assessment of knees and ankles

* MRI assessment of knees and ankles

Contacts

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Eligibility criteria

Inclusion criteria

* Aged 18-32 year

* Clinical and radiological absent or minimal arthropathy

* Severe (<1% FVIII/IX activity) or moderate haemophilia (1-5% FVIII/IX activity)

(* MRI assessment of both knees and ankles by the standardized MRI protocol in 2009/2010)

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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2014
Enrollment:	24
Type:	Actual

Ethics review

Positive opinion	
Date:	21-08-2014
Application type:	First submission

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
NTR-new	NL4603
NTR-old	NTR4754
Other	University Medical Center Utrecht : METC 14-274

Study results