# The value of MRI diagnostics in haemophilic arthropathy: a pilot study

Published: 15-07-2008
Last updated: 11-05-2024

Primary Objective: (diagnostic)• Does MRI detect structural changes of haemophilic arthropathy in knees and ankles undetected by the Pettersson score and HJHS? (Research question 1 a & b)Secondary Objective(s): (prognostic)• Can MRI predict loss...

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

## Summary

### ID

NL-OMON37969

**Source**
ToetsingOnline

**Brief title**
MRI pilot in haemophilic arthropathy

### Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Joint disorders

**Synonym**
FVIII/FIX deficiency, haemophilia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** farmaceutische industrie,Novo Nordisk,Pfizer

## Intervention

**Keyword:** arthropathy, diagnostics, haemophilia, MRI

## Outcome measures

### Primary outcome

Determinant: MRI findings according to the Lundin additive Score.

Outcome parameters:

Diagnostic study: HJHS score (T=0)

Pettersson score (T=0)

Prognostic study: delta HJHS score (T=2.5 and T=5 years)

delta Pettersson score (T=5 years)

### Secondary outcome

The association of MRI with delta HJHS after 2.5 and 5 years' interval will be adjusted for baseline HJHS score, number of joint bleeds during the observation interval, physical activity, and age.

The association of MRI with delta Pettersson score after 5 years' interval will be adjusted for baseline Pettersson score, number of joint bleeds during the observation interval, physical activity, and bone age.

# Study description

### Background summary

Repeated joint bleeds, eventually leading to crippling arthropathy, are the hallmark of haemophilia. Traditionally, outcome assessment in haemophilia has been focused on structural assessment of the six most frequently affected joints: elbows, knees, and ankles. Since the 1980s, two haemophilia specific

tools have been available: the radiological Pettersson score and the clinical joint score (or orthopaedic joint score). Both scoring systems have been adapted by the World Federation of Haemophilia, and have been widely used, in spite of their limitations. Recently, several new tools for outcome assessment in haemophilia have been developed. As result of the efforts of the International Prophylaxis Study Group (IPSG) a scoring system for structural assessment using MRI (Lundin additive score), was developed and the orthopaedic joint score was adapted into the HJHS (haemophilia joint health score) to assess more subtle joint damage. Except for a recent RCT comparing prophylactic to on demand treatment in young children with severe haemophilia (follow-up until age 6 yrs), MRI has been used in older patients to diagnose synovitis, rather than evaluate prophylactic treatment. Hence we do not know if our teenage patients with a history of a few bleeds, but very little or no arthropathy on X-ray and good clinical function, will have structural changes on MRI.
In order to study the value of this instrument in relation to the other outcome parameters and its ability to pick up early changes, a pilot study will be performed among a subset of adolescents participating in two international projects on severe and moderate haemophilia. As the power of a pilot study is limited by definition, the results on MRI will only begin to address correlation and potential discriminative value in comparison with other outcome instruments and its ability to predict future changes.
Controls will be included to distinguish haemophilia-related abnormalities from sports-related abnormalities.

## Study objective

Primary Objective: (diagnostic)
• Does MRI detect structural changes of haemophilic arthropathy in knees and ankles undetected by the Pettersson score and HJHS? (Research question 1 a & b)
Secondary Objective(s): (prognostic)
• Can MRI predict loss of function (measured by HJHS) in 2,5 and 5 years* time? (Research question 2 a & b)
• Can MRI predict X-ray changes (measured by Pettersson score) in 5 years* time? (Research question 3)

## Study design

Diagnostic: cross-sectional within cohorts from other projects.
Prospective part: follow-up will be 5 years, using routine data.

## Study burden and risks

Participants will undergo one MRI of 4 joints (4x 15 min in the MRI scan) and an X ray examination of the wrist (5 min). Remaining measurements will be

collected from available data. The risk for participants is considered minimal.
The impact of MRI studies is expected to be most pronounced and clinically most relevant in young adults and adolescents (aged 12-26): if the MRI findings warrant intensification of treatment to further reduce the number of bleeds, younger patients are expected to benefit more than older patients. Treatment will not change during the study unless aforementioned unexpected significant MRI changes warrant intensification of prophylactic treatment. This will not affect the analyses, as damage is related to bleeds only.
Controls will undergo one MRI of 4 joints (4x 15 min in the MRI scan), as well as a standardised physical examination (15-20 min) and complete two short questionnaires (10-15 min). They are not expected to benefit from or be harmed by participation in the study.

## Contacts

**Public**
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
**Scientific**
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
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

• Haemophilia A or B
• Severe (<1% FVIII/IX activity) (n=20) or moderate haemophilia (1-5% FVIII/IX activity) (n=10).
• 12-26 years of age
• Recent Pettersson scores (within two years of assessment) available
• maximum one knee or ankle with a score above 3 points
• minimal two ankles or knees with a score of 0 points
• entry clinic before age 4
Controls:
• male, 18-26 years of age
• participating in regular sports (1-3x/wk )

### Exclusion criteria

• History of inhibitors
• No access to standard care since birth (e.g. immigration from other country)
• Last Pettersson score more than 2 years before assessment
• More than one knee or ankle with a Pettersson score above 3 points
• Less than two knees or ankles with a Pettersson score of 0 points
• Extensive bleeding in knees or ankles 2/3 weeks before assessment
Controls
• contraindication for MRI assessment
• knee/ankle injuries within 8 weeks prior to MRI
* sports participation less than once weekly or more than 3 times weekly

## 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: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-03-2009 |
| Enrollment: | 56 |
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 15-07-2008 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 07-07-2009 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 12-07-2012 |
| 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 | NL20590.041.08 |