# Testing an increased visit interval scHeme UsIng web-based Self-evaluation (THUIS-study)

Published: 28-01-2022
Last updated: 05-04-2024

Our objective is to safely increase the visit interval to 6 months in JIA patients with stable disease. The skipped 3-month visit isreplaced by a self-evaluation via e-mail by EQ-5D-5L-Y and JAMAR questionnaires that will be send via Castor EDC....

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Autoimmune disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51944

**Source**
ToetsingOnline

**Brief title**
THUIS-study

### Condition

- Autoimmune disorders

**Synonym**
JIA, 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:** home monitoring, Juvenile Idiopathic Arthritis, questionnaires

## Outcome measures

### Primary outcome

The main study parameter will be the number of disease flares observed at the 6-month visit. Disease flares are defined as a JADAS score of higher than 3.

### Secondary outcome

- The number of rescheduled visits due to presumed disease worsening as well as the percentage of correctly rescheduled visits (e.g. observation of a flare during the rescheduled visit).
- The number of reminders sent for filling out the questionnaires at the 3 month moment and the number of patients that fail to home monitor themselves.

Exploratory outcomes:

- Description of events of specific interest during home self-monitoring: presumed medication related events (side effects)
- Relationship between JAMAR answers using self-evaluation and active joint count and PGA at the scheduled 6-month visit
- Validation of EQ-5D and EQ-VAS score cut-offs as indicators of stable disease.
- satisfaction with home monitoring using a separate questionnaire

# Study description

## Background summary

Juvenile Idiopathic Arthritis (JIA) is one of the most common chronic rheumatic diseases in childhood (Prakken et al., 2011). This chronic disease has a major impact on the functioning and happiness of a child (Gutiérrez-Suárez et al., 2007; Haverman et al., 2012; Sawyer et al., 2004; Tollisen et al., 2018).

Currently, when during several visits a stable low disease activity is achieved, the interval between visits is often increased by the physician. We think this decision to increase visit intervals can also be made by the patient based on a self-evaluation by filling in the JAMAR questionnaire for JIA specific measures (such as the number of involved joints, functional status and drug side-effects) and the EQ-5D-5L-Y questionnaire for overall quality of life (pain, well-being, etc.) (Otto et al., 2018; Scott et al., 2019; Wille et al., 2010).

JIA is a remitting relapsing disorder. At every clinical visit the juvenile arthritis disease activity score (JADAS) is determined. The JADAS is a composite score, including an inflamed joint count by the physician, a physician global assessment (PGA) and a patient severity score measured on a visual analogue scale (VAS) (Consolaro et al., 2009, 2014; Swart et al., 2018). Our treatment aim is to obtain the lowest (best) JADAS score possible. During routine monitoring currently performed, the scores from our electronic medical record (HIX) are transferred to our research data platform (RDP). Here we calculated the number of disease flares (JADAS score of >3) at a follow up visit in the past 5 years to be around 14%.

We want to show that patients that replace the outpatient's clinic visit by home-monitoring, thus providing the medical team with a JAMAR and EQ-5D-5L-Y, have a disease outcome that is not worse than patients that routinely visit the clinic on a 3 months interval. Possible disease worsening will be monitored by the physician together with the nurse using the answers given by the patient in the questionnaires. When deemed necessary, the physician will contact the patient and the visit can be rescheduled at the earliest time possible. Signs of such worsening are an increase in pain intensity and the number of joints involved, an increase in the duration of morning stiffness and worsening of the patient-reported overall disease severity score.

## Study objective

Our objective is to safely increase the visit interval to 6 months in JIA patients with stable disease. The skipped 3-month visit is replaced by a self-evaluation via e-mail by EQ-5D-5L-Y and JAMAR questionnaires

that will be send via Castor EDC. The
overall disease outcome, defined as the number of disease flares measured, is not worse compared with the historical data of
routine clinical care measured in the previous years (2015-2019, data present in Research Data Platform).

**Study design**

This is a non-inferiority study where a study cohort is compared to a historic control cohort.

**Intervention**

There is only one study group. All participant patients will be offered a control interval of 6 months instead of the current 3 months. All patients will complete a JAMAR and EQ-5D-5L-Y questionnaire for self evaluation. At 3 months such an evaluation will replace a hospital visit. Questionnaires will be send via e-mail using Castor EDC. If deemed necessary by the treating physician, the participant will receive a lab form for drawing blood at their general practicioner at 3 months. The lab results will be send to the research team in order to monitor toxicity of medication.

**Study burden and risks**

There is no extra burden associated with study participation. It is already current practice for our JIA patients to complete a JAMAR questionnaire during regular visits. A potential risk is worsening of disease activity without the patient noticing. Therefore, only patients in stable disease are invited to participate. The risk of a flare in this group of patients is low. Benefit is the increase in follow up interval, reducing the number of visits to the outpatient clinic. There is no study drug used.

# 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

-JIA diagnosis of >=1 year
-age 6 - 20 years
-Clinical remission, defined as cJADAS <= 3

## Exclusion criteria

-use of steroids
-not able to read or understand Dutch language
-not able or willing to use e-mail

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

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| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 28-03-2022 |
| Enrollment: | 85 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 28-01-2022 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 19-10-2022 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 21-12-2022 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

## 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 | NL78722.041.21 |

# Study results

Results posted: 28-03-2022

**First publication**
01-01-1900