# Mesenchymal stromal cells for treatment of drug resistant pediatric juvenile idiopathic arthritis

Gepubliceerd: 04-09-2013 Laatst bijgewerkt: 13-12-2022

To find out if intravenous MSC is a safe treatment for children with therapy-resistant JIA

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON21350

**Bron**
NTR

**Verkorte titel**
MSC-JIA

**Aandoening**

juvenile idiopathic arthritis

### Ondersteuning

**Primaire sponsor:** University Medical Center Utrecht
**Overige ondersteuning:** ZonMw (The Netherlands Organisation for Health Research and Development)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Total number of adverse events in the 3 months prior to MSC infusion and the number of

adverse events 3 months after MSC infusion.<br>
To offer an effective alternative for that category of JIA patients that is therapy-resistant.<br>
For this effectiveness the ACR Pediatric 70 criteria should be achieved.<br>
The ACR Pedi 70 criteria are defined as improvement of >= 70% in at least 3 of 6 core response variables used to assess disease activity with no more than 1 variable worsening by >= 30%.

# Toelichting onderzoek

### Achtergrond van het onderzoek

The main objective is to offer a safe alternative for that category of JIA patients that is therapy-resistant. We hypothesize that intravenous administration of MSC in therapy refractory JIA patients is safe and has the potential to have clinical relevant effect as measured by the ACR Pedi 30.

Aims:

1. Total number of adverse events in the 3 months prior to MSC infusion and the number of adverse events 3 months after MSC infusion.

2. The ACR Pediatric 30 criteria should be met

3. Radiological (MRI) improvement of most active large joint.

4. Improvement in laboratory parameters or biomarkers.

### Doel van het onderzoek

To find out if intravenous MSC is a safe treatment for children with therapy-resistant JIA

### Onderzoeksopzet

52 weeks after the (first) MSC injection the primary outcome will be measured and the third MRI will be made.

Also all data and materials for the secondary outcomes are collected within this time frame. This will also be the end of the study for the individual.

### Onderzoeksproduct en/of interventie

1 to maximal 3 iv MSC infusions.3 MRI scans, 4 extra visits to the hospital and 3 extra venapunctures when compared to standard treatment in the typical JIA patient

# Contactpersonen

## Publiek

UMC Utrecht, Wilhelmina Children's hospital
Intern mail address KC 03.063.0
PO Box 85090

Joost Swart
Utrecht 3500 AB
The Netherlands
+ 31 88 7554339

## Wetenschappelijk

UMC Utrecht, Wilhelmina Children's hospital
Intern mail address KC 03.063.0
PO Box 85090

Joost Swart
Utrecht 3500 AB
The Netherlands
+ 31 88 7554339

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria: In order to be eligible to participate in this study, a subject must meet all of the following criteria:

Patients (4-18 years of age) diagnosed with juvenile idiopathic arthritis according to the ILAR-criteria with active arthritis resistant to intra-articular steroids and systemic use of methotrexate and for whom no on-label indication exists for (not yet used) biologicals.

The patient is followed for adverse events via the
Pharmachild database.

Informed consent signed.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Concurrent use of biological response modifiers.

Concurrent infection, febrile illness or malignancy.

Pregnancy.

No signed informed consent.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-08-2014 |
| Aantal proefpersonen: | 6 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 04-09-2013 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL3923 |
| NTR-old | NTR4146 |
| Ander register | 2012-002067-10 : EUDRACT |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten