# UCAN CAN-DU: Canada-Netherlands Personalized Medicine Network in Childhood Arthritis and Rheumatic Disease

Published: 06-03-2019
Last updated: 12-04-2024

This non-interventional, observational cohort study, aims to standardize the assessment of disease activity in all JIA patients and correlate this to systematically acquired clinical, environmental and laboratory derived data. Ultimately, these data…

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Autoimmune disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON55655

**Source**
ToetsingOnline

**Brief title**
UCAN CAN-DU

### 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:** ZonMW;in samenwerking met Reuma Nederland

## Intervention

**Keyword:** biologicals, JIA, juvenile idiopathic arthritis

## Outcome measures

### Primary outcome

This is a non-interventional, observational cohort study, in which we aim to standardize the assessment of disease activity in all JIA patients at baseline visit, T = 6 months and T= 12 months after start of disease, start of biological therapy and stop of biological therapy.

### Secondary outcome

- To develop a disease classification system that categorizes children with arthritis based on their biology and clinical data.

- To develop a predictive tool for treatment response to 1st (or subsequent) biological

- To develop a predictive tool for successful stop of biological therapy.

- To determine disease activity at T= 2 and T =5 years after diagnosis

- To determine treatment response at T=2 and 5 year after start of biological therapy

- To register severe adverse events in our cohort in the next 5 years.

- To assess the current socioeconomic impact of this chronic disease in families with an affected child with JIA.

# Study description

### Background summary

Childhood arthritis describes a group of diseases that commonly manifest as pain, stiffness and swelling of the joints and other supporting structures. Paediatric patients, who are diagnosed with arthritis face symptoms that are debilitating, can dramatically decrease quality of life and can also extend beyond childhood into lifelong chronic rheumatic diseases. As such, providing timely and effective interventions
is crucial for improving short and long term health outcomes for children living with this disease. Children that are at high-risk of permanent joint damage due to their arthritis often require advanced therapeutic agents called biologics. One in three paediatric and adult patients currently receives biologic therapies for arthritis without any treatment end-date. The latter resulted in an estimated expenditure of $6.4 billion in the year 2000, which grew to $33 billion by 2011 within Canada alone. This same scenario was echoed in the Netherlands, where costs for biologic therapies in RA doubled from 2007 to 2011. Although biologic therapies can dramatically improve disease outcomes, adverse side effects can be associated with this course of treatment and the use of these therapies imposes substantial economic burdens on the patients, their families and society. One of the great strengths of studying diseases in children is that we can learn about the underlying pathobiology of chronic inflammation without the influences of aging, varied environmental exposures and lifestyle choices, which are often confounding factors when studying adult populations. In addition, the knowledge we gain in the area of immunology from studying children can be highly relevant and applicable to the adult populations as well.
Recent work by our team has established that patients and treatment response can be meaningfully classified using approaches that integrate comprehensive biologic and clinical data.
Our network research program, UCAN CAN-DU, will have a multi-pronged approach with a focus on the development of new concepts for standardized evaluation of disease activity outcomes, novel eHealth based patient-reported outcomes and the real-time integration of individual biological profiles. The latter will enable us to learn from every child and family - we will inform practice while caring for children and accelerating transformative care.

### Study objective

This non-interventional, observational cohort study, aims to standardize the assessment of disease activity in all JIA patients and correlate this to systematically acquired clinical, environmental and laboratory derived data. Ultimately, these data will be used to transform the current step-up treatment approach of JIA into a more personalised treatment approach. This goal requires the creation of a large, multicentre, bi-national collaborative network,

including all (academic) paediatric rheumatology expertise centres in the Netherlands and Canada. UCAN CAN DU will set the logistic and technical prerequisites to create a sustainable network driven by patient reported outcome measures.
One of the challenges when it comes to treating childhood arthritis is providing the correct treatment at the opportune time. While advanced biologic therapies are frequently used and can be highly effective, we are currently unable to accurately predict which children should start biologic therapies and which can discontinue treatment without having disease flares. The overarching goal of the UCAN CAN-DU study is to address this gap in treatment approaches and support translational research for all children with juvenile arthritis. We propose to combine multiple data types - transcriptomic, proteomic (cytokine, chemokine, matrikine, S100 proteins, and autoantibodies), immunomic and clinical data - to identify biomarkers that can provide diagnostic and prognostic information to caregivers at the bedside. We will develop a profile of biomarkers to predict treatment response and a separate set of biomarkers to predict risk of relapse.
Our work will be informed by the continued development of our preliminary disease taxonomy for juvenile idiopathic arthritis (JIA).

**Study design**

UCAN CAN-DU is a multicentre longitudinal observational cohort study that will use prospective population data of children with JIA. Biologic samples and clinical data will be prospectively collected at participating centres. All clinical, biological and patient-derived data will be collected at an aggregation point. A metadata-architect will install two-way real-time data syncing channel with databases and apps connected to the aggregation point. The standard based formats and vocabularies used to store data will also allow integration with various third party systems. This will enable us to share and integrate data in real-time into analytic models throughout the study course; hence providing a continuous real-time feedback from bench to bedside and vice versa.
The analysis of this prospective cohort will help define and confirm the biologic pathways predictive of treatment response and disease remission. This knowledge will then be used to develop a comprehensive clinical predictive tool to guide effective and safe treatment of childhood arthritis.

**Study burden and risks**

We do not anticipate any adverse effects from the study. Venipuncture from blood collection can be associated with some discomfort, and could include bruising, bleeding or fatigue. We will offer the participants a localized numbing cream or anesthetic patches to limit discomfort when possible.

No other adverse consequences are anticipated.

# Contacts

**Public**
Universitair Medisch Centrum Utrecht

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

Heidelberglaan 100
Utrecht 3584CX
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

## Inclusion criteria

For cohorts 1,2 and 3:
• <= 18 years at time of inclusion
Cohort 1 - Biologic Basis of JIA:
Active objective arthritis suspected to be JIA
- Treatment naïve
• No systemic corticosteroids in the past 4 weeks.
• No intra-articular corticosteroid injections in the past 4 weeks.
• allowed to have received NSAIDS within 6 months of diagnosis

Cohort 2 - Start Biologics
- JIA diagnosis as per ILAR criteria (all subtypes)
- Active arthritis.
For sJIA, active disease not necessarily with arthritis.
- Time of start, restart or switch biologic therapy:
e.g. failure, insufficient/partial response or intolerance to conventional DMARDs
Cohort 3 - Stop Biologics:
* JIA diagnosis as per ILAR criteria (all subtypes)
* Inactive disease discontinuing/tapering biologics for inactive disease
Cohort 4 - Extreme Phenotypes
* Unexplained systemic inflammation with arthritis/arthralgia as a part of manifestations, or;
* High suspicion of genetic contribution, or;
* Severely affected patients with difficult to control disease (ie failure of multiple classes of biologics)
- * 1 or 2 parents or siblings with a diagnosis of JIA or other arthritis related disease.

### Exclusion criteria

Cohort 1 - Biologic Basis of JIA:
* Arthritis explained by any other cause
* Joint injections as previous treatment
Cohort 2 - Start Biologics:
* Arthritis explained by any other cause
* Start on biologics as an indication for uveitis only
Cohort 3 - : Stop Biologics
* Tapering scheme > 12 months to complete biologics stop
* Continuing conventional DMARDs beyond the stop of biologics
Cohort 4 - Extreme phenotypes
*Arthritis explained by another diagnosis

## Study design

### Design

**Study type:** Observational non invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 28-03-2019 |
| Enrollment: | 1400 |
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 06-03-2019 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 12-06-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 19-08-2021 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 02-11-2021 |
| 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 | NL65212.041.18 |