CHAMP: Children with Arthritis: Monotherapy or Polytherapy. A multicentre, single-blinded, randomized treat to target, one-year follow-up clinical trial in patients with recent onset Juvenile Idiopathic Arthritis (JIA).

Published: 17-11-2015
Last updated: 17-01-2025

To study whether polytherapy (methotrexate plus sulfasalazine plus hydroxychloroquine) results in more patients with inactive disease and therefore less patients who need treatment with a TNF inhibitor after 6 months of treatment compared to primary...

Ethical review	Approved WMO
Status	Completed
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON53043

Source
ToetsingOnline

Brief title
CHAMP

Condition

- Autoimmune disorders
- Joint disorders

Synonym
arthritis, juvenile idiopathic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Kindergeneeskunde
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Antirheumatic agents, Arthritis, Children, combination, Drug therapy, juvenile

Outcome measures

Primary outcome

The primary endpoint of the study is the number of patients in both treatment

strategies who have active disease after 6 months of treatment.

Secondary outcome

- To compare side effects and tolerability of treatment in both treatment

arms

- To compare the number of patients that are treated with a TNF inhibitor after

12 months of treatment in both arms

- To compare the number of patients that need to switch to subcutaneous MTX

after 3 months of treatment in both treatment arms

- To compare ACR Pedi scores (30, 50, 70, 90) in both treatment groups at 3,

6, 9, and 12 months and the number of patients with inactive disease at 3, 9

and 12 months of treatment

- To compare functional ability and quality of life in both treatment arms

- To provide cost-effectiveness data concerning the first year of DMARD therapy

in both groups

- To identify possible predictors of response such as serologic markers,

urinary markers, genetic biomarkers and faecal microbiota

Study description

Background summary

Initial disease modifying antirheumatic drug (DMARD) therapy with methotrexate in children with juvenile idiopathic arthritis (JIA) has low efficacy (±20% inactive disease after 6 months) and is often poorly tolerated. For this reason, it has been proposed that TNF-inhibitors may be used as a first-line treatment. The response to TNF inhibitors is often more rapid, but the treatment has the downside of parenteral use and high costs. In adults with rheumatoid arthritis, polytherapy with a combination of DMARDs has been proven to be very effective. We therefore propose that polytherapy with methotrexate plus sulfasalazine plus hydroxychloroquine could be beneficial for children with juvenile idiopathic arthritis who require DMARD therapy.

Study objective

To study whether polytherapy (methotrexate plus sulfasalazine plus hydroxychloroquine) results in more patients with inactive disease and therefore less patients who need treatment with a TNF inhibitor after 6 months of treatment compared to primary MTX monotherapy in children with newly diagnosed JIA.

Study design

A multicentre, single-blinded, randomized treat to target, one-year follow-up clinical trial

Intervention

Patients are randomly assigned to one of two treatment strategies: monotherapy with methotrexate (in combination with prednisolone bridging) or polytherapy with methotrexate plus sulfasalazine plus hydroxychloroquine (in combination with prednisolone bridging). When ACR Pedi 50 is not met after 3 months of treatment, methotrexate will be given subcutaneously. When at 6 months inactive disease is not reached a TNF-inhibitor will be started.

Study burden and risks

This study focuses on the treatment of JIA and can therefore only be performed in children (2-16 years old). During the study, blood sampling and visits to

the outpatient clinic are part of regular care. The side effects of polytherapy are expected to be similar or slightly increased compared to methotrexate monotherapy. Participation in this study may lead to earlier achievement of inactive disease and therefore no need to administer methotrexate subcutaneously or to switch to (subcutaneous) biologic treatment.

Contacts

Public
Selecteer

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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

- Patients with persistent or extended oligoarticular JIA,
RF-negative polyarticular JIA, RF-positive polyiarticular JIA, psoriatic JIA,
enthesitis- related JIA or undifferentiated JIA according to ILAR
Classification criteria
- Active synovitis;
- Requiring DMARD therapy according to the treating pediatric rheumatologist.
In case of persistent oligoarticular JIA this means patients with poor clinical
prognostic factors, for example according to Beukelman;
- Age between 2-16 years;
- Treated in one of the Dutch paediatric rheumatology centers;
- A maximum of 18 months of symptoms;

Exclusion criteria

- Systemic onset Juvenile Idiopathic Arthritis - Previous
treatment with DMARDs (including study medication) or biological - Any
concurrent illness that would constitute an increased risk for side effects of
medication, is associated with an increased risk for severe infections or in
the opinion of the treating physician is a contraindication for treatment with
any of the initial therapies or participation in the trial as such. - Current
or prior history of blood dyscrasias. Abnormal safety baseline blood test e.g.
haemoglobin <= 5 mmol/l; haematocrit <= 27%; platelet count <= 125 x 109 /L; white
blood cell count <= 3.5x 109 /L; serum creatinine >= 2 times the laboratory*s
upper limit of normal; aspartate aminotransferase (AST [SGOT]) and alanine
aminotransferase (ALT [SGPT]) >= 2 times the laboratory*s upper limit of normal.
- Pregnancydie in meerd

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-09-2016
Enrollment:	130
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	enbrel
Generic name:	etanercept
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	methotrexate
Generic name:	methotrexate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	plaquenil
Generic name:	hydroxychloroquine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	prednisolone
Generic name:	prednisolone
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	salazopyrine
Generic name:	sulfasalazine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	17-11-2015
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	04-05-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	06-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	28-06-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	30-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	27-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	08-06-2021
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	26-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	09-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
EudraCT	EUCTR2014-003260-20-NL
CCMO	NL53170.058.15