Children with arthritis: monotherapy or polytherapy?

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29408

Source
NTR

Brief title
CHAMP

Health condition

juvenile idiopathic arthritis (JIA)

Dutch: juveniele idiopathische artritis (JIA)

Sponsors and support

Primary sponsor: Leiden University Medical Centre
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

The number of patients with inactive disease after 6 months of treatment

Secondary outcome

- Side effects and tolerability of treatment in both treatment arms

- Number of patients that are treated with a TNF inhibitor after 12 months of treatment in both arms

- The number of patients that need to switch to subcutaneous MTX after 3 months of treatment in both treatment arms

- ACR Pedi scores (30, 50, 70, 90) and clinical JADAS scores 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

- Functional ability and quality of life in both treatment arms

- Cost-effectiveness data concerning the first year of DMARD therapy in both groups

- Possible predictors of response, such as serologic and genetic markers

Study description

Background summary

Rationale: Initial disease modifying antirheumatic drug (DMARD) therapy with methotrexate in the

treatment of juvenile idiopathic arthritis (JIA) has a low efficacy. 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, sulfasalazine and

hydroxychloroquine could be beneficial for children with juvenile idiopathic arthritis who require

DMARD therapy.

Primary objectives: To study whether polytherapy (methotrexate, sulfasalazine and

hydroxychloroquine) results in more patients with inactive disease and therefore less patients that

need treatment with a TNF inhibitor after 6 months of treatment compared to primary MTX

monotherapy in children with newly diagnosed JIA.

Secondary objectives:

- 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) and JADAS scores 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

Study design: A multicenter, single-blinded, randomized, treat to target, one-year follow-up clinical

trial in patients with recent onset JIA.

Study population: Children (2-16 years old) with JIA and active disease.

Intervention: Patients are randomly assigned to one of two treatment strategies: monotherapy with

methotrexate (in combination with prednisolone bridging) or polytherapy with methotrexate,

sulfasalazine and hydroxychloroquine (in combination with prednisolone bridging). When

improvement is not sufficient after 3 months of treatment (according to JADAS10 cut-off values),

methotrexate will be switched to subcutaneous administration in either strategy. When at 6 months

inactive disease (according to modified Wallace criteria1) is not reached, a TNF-inhibitor will be

started.

Main study endpoint: The number of patients with inactive disease after 6 months of treatment.

Nature and extent of the burden and risks associated with participation, benefit and group

relatedness: 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. Polytherapy may lead to earlier achievement of inactive

disease and therefore no need to administer methotrexate subcutaneously or to switch to

(subcutaneous) biologic treatment.

Study objective

Combinationtherapy with methotrexate, sulfasalazine en hydroxychloroquine will result in more patients with inactive disease and therefore less patients that need an TNF-inhibitor after 6 months of treatment than treatment with methotrexate alone in children with recently diagnosed juvenile idiopathic arthritis.

Study design

baseline, 3,6,9 and 12 months

Intervention

Arm 1: methotrexate monotherapy

Arma 2: combination therapy with methotrexate, sulfasalazine en hydroxychloroquine

Contacts

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Eligibility criteria

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 Beukelman7

- Age between 2-16 years

- Treated in one of the Dutch paediatric rheumatology centres

- A maximum of 18 months of symptoms

Exclusion criteria

- Systemic onset Juvenile Idiopathic Arthritis

- Patients with oligoarticular JIA with mono-arthritis of a knee

- Previous treatment with DMARDs (including study medication) or a 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 ¡Ü 5 mmol/l; haematocrit ¡Ü 27%; platelet count ¡Ü 125 x 109 /L; white blood cell count ¡Ü 3.5x 109 /L; serum creatinine ¡Ý 2 times the laboratory¡¯s upper limit of normal; aspartate aminotransferase (AST [SGOT]) and alanine aminotransferase (ALT [SGPT]) ¡Ý 2 times the laboratory¡¯s upper limit of normal.

- Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-06-2016

Enrollment:	130
Type:	Anticipated

Ethics review

Positive opinion Date:	01-06-2016
Application type:	First submission

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
NTR-new	NL5742
NTR-old	NTR5887
Other	NL 5317005815 : ABR

Study results