BeSt for kids: comparing treatment strategies in juvenile idiopathic arthritis.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26585

Source
Nationaal Trial Register

Brief title
BeSt for kids

Health condition

juvenile idiopathic arthritis
jeugdreuma
treatment strategy
behandelings strategie

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: Wyeth Pharmaceuticals

Intervention

Outcome measures

Primary outcome

1. Time to remission.

2. Time to flare.

Secondary outcome

1. PRINTO-score.

2. Quality of Life.

3. Safety.

4. Joint damage.

5. Costs of medication.

Nature and extent of the burden and risks associated.

Study description

Background summary

Disease outcome for children with all subsets of juvenile Idiopathic Arthritis is disappointing. As longstanding disease activity leads to damage of joints and possible incapacity early introduction ie within the window of opportunity of "powerfull" medication is compared with the classic treatment. This early intervention may induce rapid remission enabling the treating phycisian to taper and stop this medication.

Study objective

treatment strategy will induce a swift remission which will ameliorate the outcome.

Study design

three-monthly visits

two year follow-up

Intervention

After informed consent, patients will be randomised to one of 3 treatment strategies:

1. Initial sulfasalazine 50 mg/kg/dag, next methotrexate 10 mg/m2/week (followed by MTX

dose increase 15 mg/m2/week), next etanercept 0,8 mg/kg/week + MTX10 mg/m2/week.

2. Initial MTX 10 mg/m2/week and prednisone bridging (followed by MTX dose increase 15 mg/m2/week), next etancercept 0,8 mg/kg/week + MTX 10 mg/m2/week.

3. Initial etanercept 0,8 mg/kg/week with MTX 10 mg/m2/week.

Primary target:

ACR 50, next target: remission according to definition of Wallace.

Tapering of drugs after three months clinical remission according to Wallace for oligoarticular JIA and six months for polyarticular JIA.

There is no controlgroup.

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Eligibility criteria

Inclusion criteria

1. All new patients with JIA with the oligo- and polyarticular subtype, treated in one of the Dutch pediatric rheumatology centers with a maximum of 18 months symptoms with active disease despite 4 months NSAIDs and/or intra-articular steroids.

Exclusion criteria

1. Systemic JIA

2. Pretreatment with methotrexate, prednisone and/or etanercept (for > 3 months)

3. Bone marrow hypoplasia

4. Sepsis or risk of sepsis

5. Current or recent infections (last three months), including chronic or localized: evidence of active CMV or EBV, infectious hepatitis, active pneumocystis carinii, drug resistant atypical mycobacterium or other bacterial infections. Documented HIV infection

6. Positive signs or symptoms, by physical examination or PPD and/or X-thorax, of latent or active tuberculosis in patients who cannot/will not be treated with the appropriate antibiotic treatment, as recommended by the local specialist

7. History of lymphoproliferative disease including lymphoma or signs suggestive of possible lymphoproliferative disease, such as lymphadenopathy of unusual size or location (such as nodes in the posterior triangle of the neck, infraclavicular, epitrochlear, or periaortic areas), or splenomegaly

8. Other comorbidity that prevents treatment with oral corticosteroids and/or sulfasalazine and/or methotrexate and/or etanercept, or other comorbidity that, in the opinion of the pediatrician, prevents participation in the trial

9. Vaccination with live vaccine in last 4 weeks, or expected to require such vaccination during the course of the study

10. Previous clinical trial involvement in last 3 months

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	180
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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	NL1504
NTR-old	NTR1574
Other	MEC LUMC : Bestforkids
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
Publications:

Treat to target (drug-free) inactive disease in DMARD-naive juvenile idiopathic arthritis: 24-month clinical outcomes of a three-armed randomised trial. Hissink Muller P, Brinkman DMC, Schonenberg-Meinema D, van den Bosch WB, Koopman-Keemink Y, Brederije ICJ, Bekkering PW, Kuijpers TW, Van Rossum M, van Suijlekom-Smit LW, van den Berg JM, Boehringer S, Allaart CF, Ten Cate R. Ann Rheum Dis. 2018 Oct 11. pii: annrheumdis-2018-213902. doi: 10.1136/annrheumdis-2018-213902.

A comparison of three treatment strategies in recent onset non-systemic Juvenile Idiopathic Arthritis: initial 3-months results of the BeSt for Kids-study. Hissink Muller PC, Brinkman DM, Schonenberg D, Koopman-Keemink Y, Brederije IC, Bekkering WP, Kuijpers TW, van Rossum MA, van Suijlekom-Smit LW, van den Berg JM, Allaart CF, Ten Cate R. Pediatr Rheumatol Online J. 2017 Feb 6;15(1):11. doi: 10.1186/s12969-017-0138-4.

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