B-vit in the joint

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20367

Source
Nationaal Trial Register

Health condition

Juvenile idopathic arthritis, JIA, juvenile rheumatoid arthritis

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: WKZ research fund UMC Utrecht
Vrienden WKZ

Intervention

Outcome measures

Primary outcome

In this phase II trial essential preliminary information will be gained on the peak NAM levels in the synovial fluid.

Secondary outcome

None

Study description

Background summary

In Juvenile Idiopathic Arthritis (JIA) there is a distortion in immunological balance between regulatory T cells (Treg) and effector T cells (Teff). Enhancing the suppressive function of Treg next to suppressing activation of Teff and thereby restoring this balance is therefore a promising novel therapeutic strategy. Current treatment, like DMARDS and biologicals, however focuses primarily on influencingTeff. Interestingly, in the past few years it was found that Vitamin B3, also known as nicotinamide (NAM) stabilizes FOXP3 expression via inhibition of the histone deacetylase SIRT1. Through this mechanism it has the potential to beneficially affect this immunological balance by positively influencing regulatory T cell function. In addition, most recent research shows that, next to the effect on Treg, nicotinamide showed to have an inhibitory effect on Tcell proliferation and activation. Treatment with nicotinamide could therefore influence both sides of the equation.

We envision that NAM maintenance treatment, when combined with established immunosuppressive treatment, could help restore the immunological balance and hereby contribute to gaining and maintaining remission in JIA patients. This trial aims to be a first step in the preparation of a large phase III clinical trial to elucidate on the potential role of Vitamin B3 in the treatment of JIA.

NAM, well known as a dietary supplement, has also been extensively studied in humans in a variety of diseases in both children and adults. However, the bioavailability of NAM in patients with JIA at the side of inflammation, and therefore it’s potential as a therapeutic agent, is yet unknown. The primary objective of this open label, phase II study is therefore to assess the penetration of orally ingested NAM in the synovial fluid. Klik voor meer informatie

There will be 6 oligo- or poly-articular JIA patients included in the study from the age of 16 years and older with active disease and a clinical indication for intra-articular corticosteroid injection. They will receive high dose NAM (1,8g/m2/day) for the duration of 3 days after which NAM levels will be detected in the synovial fluid.

Study objective

Synovial fluid levels of high dosed oral intake Vitamin B3 are at least 10% of plasma levels

We envision that NAM maintenance treatment, when combined with established immunosuppressive treatment, could help restore the immunological balance and hereby contribute to gaining and maintaining remission in JIA patients. This trial aims to be a first step in the preparation of a large phase III clinical trial to elucidate on the potential role of Vitamin B3 in the treatment of JIA

Study design

3 days

Intervention

Additional NAM therapy with 1,8g/m2/day in 3 doses for the duration of 3 days before intra-articular corticosteroid injection.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with a diagnosis of oligo-articular or poly-articular JIA with active disease in 1 or multiple joints and an indication for intra-articular corticosteroid injection.

- Age of 16 years or older and under treatment of the pediatric rheumatology department of the WKZ/UMC Utrecht.

Exclusion criteria

- No informed consent possible by patient

- Inability to take oral medication

- Participation in other interventional trials

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2018
Enrollment:	6
Type:	Anticipated

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	NL7085
NTR-old	NTR7283
Other	EudraCT : 2018-002245-11

Study results