B-vit in the joint

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20367

Bron
NTR

Aandoening

Juvenile idopathic arthritis, JIA, juvenile rheumatoid arthritis

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: WKZ research fund UMC Utrecht
Vrienden WKZ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

3 days

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- No informed consent possible by patient

- Inability to take oral medication

- Participation in other interventional trials

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2018
Aantal proefpersonen:	6
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7085
NTR-old	NTR7283
Ander register	EudraCT : 2018-002245-11

Resultaten