Assessing penetration of high dose Nicotinamide (Vitamin B3) in synovial fluid

Published: 20-08-2018
Last updated: 11-04-2024

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...

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

Summary

ID

NL-OMON48653

Source
ToetsingOnline

Brief title
B-vit in the joint

Condition

- Autoimmune disorders

Synonym
Juvenile idiopathic arthritis, juvenile rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: JIA, NAM, nicotinamide, Vitamin B3

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

not applicable

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.

Study objective

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 study is therefore to assess the penetration of orally ingested NAM in the synovial fluid.

Study design

open label, phase II study

Intervention

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

Study burden and risks

Due to the study design the burden of participation of this study is considered minimal due to a very short duration of treatment and by combining blood sampling with blood sampling for routine clinical care, with the exception of 1 capillary blood sampling. No serious adverse events are expected since the very short duration of treatment and the extensive previous experience with use of high dose NAM in clinical trials in both children and adults for extensive periods. Due to the short duration of treatment It is not expected that participation is beneficial to the patients.

Contacts

Public
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3584EA
NL
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3584EA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	06-09-2019
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Nicotinamide
Generic name:	Nicotinamide

Ethics review

Approved WMO Date:	20-08-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-01-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2018-002245-11-NL

Register	ID
CCMO	NL66203.041.18

Study results

Date completed:	02-07-2021
Actual enrolment:	6