I CEA. Induction of Cure in Early Arthritis A single blind randomized clinical trial

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initial treatment with baricitinib results in more rapid remission and more sustained drug free remission compared to initial treatment with NSAIDs or methotrexate

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

Samenvatting

ID

NL-OMON29280

Bron
Nationaal Trial Register

Verkorte titel
I CEA

Aandoening

undifferentiated arthritis

Ondersteuning

Primaire sponsor: Eli Lilly and Company
Overige ondersteuning: Eli Lilly and Company

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Percentage in remission at 3 months. 2. Percentage in sustained (at least 6 previous months) drug free remission.

Toelichting onderzoek

Achtergrond van het onderzoek

A newly diagnosed arthritis, where the cause is not yet clear (so-called undifferentiated arthritis, UA), can go into spontaneous remission, or become chronic and potentially progress to rheumatoid arthritis. At presentation it is not yet clear how things will develop, and therefore it is difficult to decide who to treat it. Suppression of symptoms with NSAIDs and a local corticosteroid injection may be sufficient, or it is necessary to start an antirheumatic treatment as rapidly as possible, to prevent progression and maybe induce cure. If the latter is true, we need to start with the most effective treatment, but which that is, is also not clear. Therefore we propose to invite patients with previously untreated undifferentiated arthritis to participate in this trial, where they will be randomized to either symptomatic treatment with NSAIDs and a local injection (arm 1), or to (as well) methotrexate, a slow-acting antirheumatic drug (arm 2), or baricitinib, a fast-acting antirheumatic drug (arm 3). Clinical evaluation by an independent joint assessor every three months will determine if remission is achieved or not. If not, medication will be changed: patients in arm 1 will be randomized to either arm 2 or arm 3, patients in arm 2 will switch to treatment according to arm 3, and vice versa. If remission is achieved on NSAIDs, they can be stopped. If remission is achieved on MTX, this can be stopped after an additional 6 months (for fear of relapse after stop), and if remission is achieved on baricitinib, patients will again be randomized, to either stop immediately, or continue for an additional 6 months. Total follow-up time per patient will be 18 months. There are 2 primary endpoints: percentage in remission at 3 months, and percentage in sustained (at least 6 previous months) drug free remission at 18 months.

Doel van het onderzoek

initial treatment with baricitinib results in more rapid remission and more sustained drug free remission compared to initial treatment with NSAIDs or methotrexate

Onderzoeksopzet

February 2020 MEC approved, April 2020 first patient included, expected inclusion period 3 years, follow-up time per patients 18 months

Onderzoeksproduct en/of interventie

All arms: one intraarticular or intramuscular injection with corticosteroids (40 mg methylprednisolone or equivalent). Arm 1: start with NSAID (naproxen 2 dd 500 mg or equivalent). If no remission after 3 months: randomize to treatment according to arm 2 or arm 3. Arm 2: start with methotrexate 15 mg/week increased to 25 mg/week by week 4 or highest tolerated dose (oral or subcutaneous). NSAID or analgetic allowed. If no remission after 3 months: switch to baricitinib according to protocol of arm 3. In case remission is achieved on MTX: continue for 6 months then taper in 4 weeks to nil. In case of disease flare during or after tapering: switch to baricitinib. Arm 3: start with baricitinib 4 mg/day. NSAID or

analgetic allowed. If no remission after 3 months: switch to methotrexate according to protocol of arm 2. In case remission is achieved on baricitinib: randomize to either immediate discontinuation or continuation for 6 more months. In case of disease flare after remission: switch to methotrexate.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

18 years or older, able to give written informed consent (in Dutch or English) and fill out questionnaires in Dutch (or English version, if available), undifferentiated arthritis with symptom duration <1 year, not fulfilling classification criteria for rheumatoid arthritis, other diagnoses causing the arthritis rejected, Disease Activity Score >1.6

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Contraindications to use of study medication or reasonable alternatives
Wish to become pregnant, breastfeed or father a child during the study
Alcohol- or substance abuse
Immuno-compromised state either based on co-morbidity or co-medication
Leucopenia <3*10^9/l, and/or neutropenia <1*10^9/l

Hemoglobin <5 mmol/l
Increased liver enzymes > 3x upper limit of normal
Renal insufficiency with estimated creatinine clearance <40%
Interstitial lung disease as seen on X-thorax
Maintenance treatment with corticosteroids exceeding prednisone 10 mg daily or equivalent
Active or ongoing chronic infection, (recurrent) serious infection(s) in past 4 months, latent TB who refuse anti-tuberculous treatment, hepatitis B with positive DNA viral load or hepatitis C with positive RNA viral load, patients with anti-HB2 and anti-HBc antibodies who refuse monitoring of hepatitis B DNA expression

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-04-2020
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL8195
Ander register	METC LUMC : not yet available, EUDRACT nr is 2019-004359-35

Resultaten

Samenvatting resultaten
expected in leading rheumatology journals