De COVID I2 studie: onderzoek naar het doorgebruiken of tijdelijk onderbreken van immuun-modulerende medicijnen bij patiënten die een infectie krijgen.

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Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Auto-immuunziekten
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22848

Bron
NTR

Verkorte titel
COVIDI2

Aandoening

- Auto-immuunziekten

Aandoening

Rheumatoid arthritis

Psoriatic arthritis

Axial spondyloarthritis

Immune mediated inflammatory diseases

Inflammatory rheumatic diseases

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: Sint Maartenskliniek

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten
Proportie patiënten met een ernstige infectie (grade 3 of meer volgens de Common Toxicity Criteria for Adverse Events (CTCAE) versie 5.0).

Toelichting onderzoek

Achtergrond van het onderzoek

Immunomodulatory agents (IA) are widely used (>200,000 patients in the Netherlands) for the treatment of patients with immune-mediated inflammatory diseases (IMIDs) including rheumatoid arthritis, psoriatic arthritis, axial spondylarthritis, psoriasis and inflammatory bowel disease, and they are in general associated with a modestly increased risk of infection. However, it is not clear what risk factors for infection are, and whether it is wise to temporary interrupt IA treatment during an infection. Recently, the COVID-19 pandemic has dramatically increased the urgency to provide answers to these questions, especially since, surprisingly, some IA seem to be effective treatment against COVID-19. Therefore, the objectives of this study are to: 1) To assess the effect of continuation of IA treatment in IMID patients during an infection compared to temporary interruption of the IA treatment with regard to serious infection, and 2) to study the incidence and risk factors for infection in IMID patients using IA, with special attention for COVID-19. This study is a two arm, open-label pragmatic, explorative randomized controlled strategy study, among IMID patients using IA in the Netherlands. Adult patients with rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, psoriasis and inflammatory bowel disease using IA (except monotherapy rituximab or glucocorticoids) in any dose without a current infection will be included and randomized into either the intervention or control group. The intervention consists of

continued IA treatment and the control condition is interruption of IA treatment until the infection is resolved, all in addition to standard of care. Main study parameters/endpoints: The primary outcome is serious infection (resulting in hospitalization, intravenous antibiotics, admission to the intensive care or death)

Doel van het onderzoek

As this is an explorative design, no formal hypothesis is made. However, our sample size is based on a difference of 2.5% or more in cumulative incidence of serious infections when continuing IA, hypothesizing that patients who continue their IA in case of an infection experience less severe infections compared to patient who temporarily interrupt IA.

Onderzoeksopzet

Patients will be followed for 12 months, receiving questionnaires at baseline and one each following month. If a patient experiences an infection at t = 12 months, he/she will be followed until the infection has passed. In addition, data will be collected in case of an infection.

Onderzoeksproduct en/of interventie
Doorgaan met immuunmodulerende medicatie tijdens een infectie

Contactpersonen

Publiek

Sint Maartenskliniek
Merel Opdam

0640502845

Wetenschappelijk

Sint Maartenskliniek
Merel Opdam

0640502845

Deelname eisen

Leeftijd
Adolescenten (16-17 jaar)

Adolescenten (16-17 jaar)
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Clinical diagnosis of at least one of the following IMIDs: Rheumatoid arthritis (RA), psoriatic arthritis (PsA), axial spondyloarthritis (axSpA), psoriasis (PsO) or inflammatory bowel disease (IBD) (i.e. Crohns disease (CD) or ulcerative colitis (UC). - Age ≥ 16 years - Using one or more of the following immunomodulating agents (IA) from table 1 in any dose. Monotherapy rituximab and glucocorticoids are exempts because rituximab cannot be stopped due to long half-life time and post pharmacokinetic effects on b-cell depletion, and glucocorticoids because stopping is associated with secondary hypocortisolism. - Not experiencing any clinical infection at time of inclusion (based on check in electronic health record and as reported by patient at inclusion). - Ability to read and communicate well in Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Use of the following immunomodulating agents in monotherapy and through intravenous administration: rituximab, tocilizumab or abatacept. This because the contrast between stopping and continuation is expected to be low, as the treatment intervals are high, and intravenous medication is not easily provided in case of hospital admission. - Use of glucocorticoids (GC) in monotherapy, because stopping of GC is not feasible due to risk of GC use induced hypocortisolism - Not willing to be randomized to either intervention or control condition. - Not being able to be followed for 12 months, because of planned relocation or short life expectancy.

Onderzoeksopzet

Opzet

Fase onderzoek:	4
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	08-10-2020
Aantal proefpersonen:	2200
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Individual de-identified participant data will be made available to researchers who provide a methodologically sound proposal to achieve aims in the approved proposal or for individual participant data meta-analyses. Data requestors will need to sign a data access agreement.

Ethische beoordeling

Goedgekeurd WMO

Datum:	20-07-2020
Soort:	Eerste indiening
Toetsingscommissie:	METC Oost-Nederland
	p/a Radboudumc, huispost 628,
	Postbus 9101
	6500 HB Nijmegen
	024 361 3154
	commissiemensgebondenonderzoek@radboudumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54899
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8922
CCMO	NL73479.091.20
OMON	NL-OMON54899

Resultaten