COntinuation Versus Interruption of Immunomodulating Drugs in case of an Infectious disease in immune mediated inflammatory disease (IMID) patients, with special attention for COVID-19

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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.2) to study the incidence and risk factors for infection in IMID...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON54899

Source
ToetsingOnline

Brief title
COVID I2

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders
- Joint disorders

Synonym
Immune mediated inflammatory diseases; autoimmune diseases

Research involving

Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Sint Maartenskliniek;crowdfunding

Intervention

Keyword: COVID-19, immune mediated inflammatory disease (IMID), Immunomodulating drugs, Infectious disease

Outcome measures

Primary outcome

The primary outcome is serious infection (resulting in hospitalization,

intravenous antibiotics, admission to the intensive care or death) defined as

Grade 3 or higher based on the Common Toxicity Criteria for Adverse Events.

Secondary outcome

Secondary outcomes include: medication use, disease flares, adverse events and

costs

Study description

Background summary

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.

Study objective

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.
2) to study the incidence and risk factors for infection in IMID patients using IA, with special attention for COVID-19.

Study design

This study is a two arm, open-label, pragmatic, explorative randomized controlled superiority strategy study, among IMID patients using IA in the Netherlands.

Intervention

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.

Study burden and risks

This collaborative project will provide evidence informing many care providers potentially leading to improved patient outcomes (shorter/less severe infections) and improved cost-effectiveness (less prolonged infection/hospitalization/death). Participants will be burdened with several questionnaires during 12 months, and a small risk/chance of a more/less severe infection when randomised to a possibly inferior/superior treatment strategy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Clinical diagnosis of one of a 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 immunomodulating agents (IA) in any dose (agents listed in protocol)
- Not experiencing any clinical infection at time of inclusion
- Ability to read and communicate well in Dutch

Exclusion criteria

- Use of the following immunomodulating agents in monotherapy and through intravenous administration: rituximab, tocilizumab, abatacept.
- Use of glucocorticoids in monotherapy
- Not willing to be randomized into intervention or control condition.
- Not being able to be followed for 12 months, because of planned relocation or short life expectancy.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2020
Enrollment:	2200
Type:	Actual

Ethics review

Approved WMO Date:	20-07-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-09-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-06-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-01-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22848
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL73479.091.20
OMON	NL-OMON22848