Pragmatic trial baricitinib versus First biological in *Tight Control* Patients suffering from Rheumatoid Arthritis (PERFECT)

Published: 18-02-2019
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To demonstrate non-inferiority of a T2T strategy in which conventional synthetic disease modifying drugs (csDMARDs) refractory RApatients are initially treated with tsDMARD baricitinib versus the comparable T2T strategy in which patients are...

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

Summary

ID

NL-OMON48248

Source
ToetsingOnline

Brief title
PERFECT

Condition

- Autoimmune disorders

Synonym
Rheumatoid arthritis/ "rheumatism"

Research involving
Human

Sponsors and support

Primary sponsor: Overige Centra

Source(s) of monetary or material Support: Deze 'investigator initiated" studie wordt deels gefinancierd uit eigen middelen en deels door een financiële bijdrage van Eli Lilly.,Eli Lilly

Intervention

Keyword: Pragmatic trial, Rheumatoid arthritis, treat to target

Outcome measures

Primary outcome

The primary endpoint is non-inferiority of tsDAMRD f irst versus TNFi first in

terms of ACR50 response at 12 weeks.

Secondary outcome

* To test for superiority of baricitinib first versus TNFi biological first in

c sDMARDs refractory RA patients in terms of ACR response,

in case of non-inferiority of baricitinib first.

• To evaluate safety of baricitinib versus b iological (TNFi) first in csDMARDs

refractory RA patients.

• To compare time to first remission and time to persistent remission between

treatment arms.

• To compare radiographic outcomes between treatment arms.

• To compare patient reported outcomes between treatment arm s.

• To compare health economical outcomes between treatment arm s.

Study description

Background summary

Outcomes of patients with rheumatoid arthritis (RA) have improved markedly over the last decades, mainly due to the availability of

novel biological therapies and the practice of adjusting treatment to ensure that predefined disease activity targets are met and maintained over time, i.e. treat to target (T2T). Despite these developments, sustained disease control still cannot be achieved in a substantial sub-population of patients in clinical practice. Recently, a new class of so called targeted synthetic disease modifying drugs (tsDAMRD) has become available as a potential additional second line treatment option for patients with RA. However, not much is currently known about the real-world benefits these medications provide when applied within contemporary T2T based management strategies.

Study objective

To demonstrate non-inferiority of a T2T strategy in which conventional synthetic disease modifying drugs (csDMARDs) refractory RA patients are initially treated with tsDMARD baricitinib versus the comparable T2T strategy in which patients are initially treated with a biological tumor necrosis factor inhibitor (TNFi) in a pragmatic randomized trial.

Study design

48-week multi-center, open label, pragmatic, non-inferiority trial.

Intervention

Patients will be randomized (1:1) to a treatment strategy starting with tsDMARD or a treatment strategy starting with TNFi. Patients will be followed up over the course of 48 weeks with scheduled clinic visits at 0, 12, 24, 36, and 48 weeks, and will also be encouraged to schedule visits if they experience a disease flare or adverse events in between scheduled visits. At each visit, disease activity guided therapeutic adjustments will be made as necessary, with the aim of achieving clinical remission. In both groups, therapeutic adjustments include the option to taper or switch medication, depending on the clinical status of the patient.

Study burden and risks

All medicinal products used in this study have marketing authorization for patients with rheumatoid arthritis, are recommended in international guidelines for the target population of this pragmatic trial and all medicinal products are prescribed at indicated dosages. Monitoring procedures for this study comply with the CBO guidelines for rheumatoid arthritis. The study therefore imposes

a similar risk and burden on patients as routine clinical care.

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 RA
• Active disease defined a s DAS28> 3.2
• Former treatment according to T2T prin ciples, at the discretion of the attending rheumatologist, i.e. past treatment decisions informed by disease activity measurements
• Previous use of at least one csDMARD

Exclusion criteria

• Disease duration >5 years
• Previous treatment with any biological DMARD or tsDMARD
• Contraindication for either TNFi or JAK inhibitor
• Latent or active tuberculosis
• Active or recurrent infections
• 3x upper limit of normal ALAT
• GFR < 30 ml/min.
• Failure to provide written informed consent

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-09-2019
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	olumiant 2 mg
Generic name:	Baricitinib 2 mg
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	olumiant 4 mg
Generic name:	Baricitinib 4 mg
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	18-02-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-05-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-05-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-07-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-08-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-08-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-09-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	08-10-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-12-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-02-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-02-2020
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-000505-72-NL
CCMO	NL68883.091.19
Other	NL7547