Research into lower dosing of tofacitinib (Xeljanz®) when used in combination with cobicistat (Tybost®), a drug that reduces drug breakdown

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26019

Source
Nationaal Trial Register

Brief title
PRACTICAL

Health condition

Rheumatoid Arthritis, Psoriatic Arthritis

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: VGZ, a Dutch health care insurer

Intervention

Outcome measures

Primary outcome

Bio-equivalence of tofacitinib BID and tofacitinib + cobicistat QD, defined as the relevant

steady state pharmacokinetic parameters (average concentration at steady state (Cavg,ss)/Area Under the Curve (AUC0-24), the 90% confidence interval of the geometric mean ratio falling entirely between 75% and 125%.

Secondary outcome

Secondary parameters are safety, efficacy (DAS28-CRP) and patient preference.

Study description

Background summary

Tofacitinib, a JAK-inhibitor which is proven effective for the treatment of rheumatoid arthritis, is mainly metabolized by CYP3A4. Cobicistat is a selective CYP3A4 inhibitor, currently used as boosting drug for antiretroviral drugs. This research will investigate whether treatment with tofacitinib 5 mg QD in combination with cobicistat 150 mg QD is bio-equivalent to the standard treatment tofacitinib BID, in patients with rheumatoid arthritis.

Study objective

We hypothesize that tofacitinib 5 mg QD in combination with cobicistat 150 mg QD is bio-equivalent to tofacitinib 5 mg BID

Study design

• T1: First visit for PK curve sample collection (approx. 2 weeks)
• T2: Second visit for PK curve sample collection (4-6 weeks)

Intervention

tofacitinib QD with cobicistat QD

Contacts

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Eligibility criteria

Inclusion criteria

• Rheumatoid arthritis (either 2010 ACR RA and/or 1987 RA criteria and/or clinical diagnosis of the treating rheumatologist, fulfilled at any time point between start of the disease and inclusion)
• Patients using tofacitinib for ≥ 2 weeks in the standard dose of 5mg BID. In addition, for patients that have used tofacitinib >3 months, it is required that a good response is achieved defined as a DAS28-CRP < 2.9 or the judgement of the rheumatologist that disease activity is low.
• Patient informed consent, ≥16 years old and mentally competent
• Ability to measure the outcome of the study in this patient (e.g. patient availability; willing and being able to undergo repeated serum samples)
• Ability to read and communicate well in Dutch

Exclusion criteria

• Concomitant use of inducers or potent inhibitors of CYP3A4 or moderate inhibitors of CYP3A4 and potent inhibitors of CYP2C19, or medication sensitive to changes in metabolism as a result of cobicistat co-treatment, as assessed with the KNMP “G-standaard” unless an alternative is listed in Table 1.
• Known contra-indications for treatment with cobicistat in line with the summary of product characteristics.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-05-2019
Enrollment:	30
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48994
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7766
CCMO	NL65634.091.18
OMON	NL-OMON48994

Study results