

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	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 ( $C_{avg,ss}$ )/Area Under the Curve (AUC<sub>0-24</sub>), 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

## Public

Sint Maartenskliniek  
Celeste van der Togt

024 3272793

## Scientific

Sint Maartenskliniek

## 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  $\geq 2$  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,  $\geq 16$  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