Precision dosing of infliximab (IFX): the efficacy and economic effect of *precision dosing* of maintenance treatment with IFX in comparison with standard IFX maintenance treatment in inflammatory bowel disease.

Published: 16-02-2015
Last updated: 21-04-2024

Aim of this study is to investigate the efficacy of *precision dosing* IFX maintenance treatment in comparison with standard IFX maintenance treatment in IBD patients in clinical remission.

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

Summary

ID

NL-OMON42154

Source
ToetsingOnline

Brief title
Precision dosing of infliximab

Condition

- Gastrointestinal inflammatory conditions

Synonym
IBD, Inflammatory Bowel disease

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: crohn's disease, infliximab, therapeutic drug monitoring, ulcerative colitis

Outcome measures

Primary outcome

Primary endpoint: Proportion of patients with sustained clinical remission (based on HBI or PM). Secondary endpoints include: annual costs of IFX treatment per patient, total annual medical costs, side effects, (sustained) biochemical remission, adverse events, quality of life, IFX trough level and IFX antibodies (with an assay allowing presence of drug).

Secondary outcome

Secondary endpoints include: annual costs of IFX treatment per patient, total annual medical costs, side effects, (sustained) biochemical remission, adverse events, quality of life, IFX trough level and IFX antibodies (with an assay allowing presence of drug).

Study description

Background summary

Infliximab (IFX) is highly effective in inducing and maintaining remission in patients with inflammatory bowel disease (IBD). However, a large proportion of patients will eventually lose response to IFX. Therefore, strategies to improve the outcome of maintenance treatment with IFX are required. Retrospective analyses suggest that adjusting IFX treatment in order to achieve IFX trough

levels (TL) above a well-defined therapeutic threshold will improve the outcome of IFX treatment.

Study objective

Aim of this study is to investigate the efficacy of *precision dosing* IFX maintenance treatment in comparison with standard IFX maintenance treatment in IBD patients in clinical remission.

Study design

Open, randomized, controlled trial.

Intervention

Patients in the intervention arm will receive individualized treatment with variable IFX dosing AND/OR intervals guided by a Bayesian pharmacokinetic model, aiming to achieve an IFX TL of 3 µg/ml. Patients in the control group will continue to receive the same IFX treatment regimen that was given prior to inclusion without dose adaptation. In the control group, treatment adjustments will only be made in case of signs of active disease, in accordance to current routine care but these patients will be considered as failures to their treatment.

Study burden and risks

Participation will result in additional blood sampling, since IFX serum concentration will be measured every 8 weeks. All other laboratory tests can be considered as routine care. Patients in the intervention group with IFX TLs >3 will receive treatment de-escalation (interval elongation and/or dose reduction) as indicated by the Baysian model. Current evidence indicates that an IFX TL of 3 suffices. Patients in the intervention group with TLs <3 will receive treatment escalation (interval shortening and/or dose increase). We hypothesize that this will result in a higher chance of remaining in clinical remission.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diagnosis of CD or UC based on endoscopy and pathology
18 years or older
Clinical remission, based on a Harvey Bradshaw Index (HBI) score *4 or a Partial Mayo (PM) score *2, for CD and UC
Scheduled IFX maintenance treatment, regardless of interval/dosing

Exclusion criteria

A history of stenotic IBD requiring dilatation and or resectional surgery in the past year

Study design

Design

Study phase:	4
Study type:	Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2015
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Remicade
Generic name:	infliximab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Not approved Date:	18-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-05-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2014-004771-23-NL
CCMO	NL51452.018.14