Trough level related side-effects of adalimumab therapy in patients with inflammatory bowel disease in clinical and biochemical remission, a cross-sectional cohort study

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Primary ObjectiveThe primary objective of this study is to assess whether high ADA serum levels lead to more side effects compared to therapeutic ADA levels in CD and UC patients who are in clinical and biochemical remission.Secondary ObjectiveThe…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON40963

Source
ToetsingOnline

Brief title
STADA: Side effects Trough level ADA

Condition

- Gastrointestinal inflammatory conditions

Synonym
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: Adalimumab, IBD, side-effects, troughlevel

Outcome measures

Primary outcome

The main study parameter is serum ADA trough level concentrations (the serum concentration just before the next injection).

Secondary outcome

Secondary study parameters:

Secondary parameters are the skinscore, VAS-scores; Joint/Fatigue, the MFI, SF-36, FACIT and IBDQ.

Other study parameters:

Clinical Colitis Activity/Harvey Bradshaw Index, serum TSH, vitamin D, Hb, Leukocytes, Thrombocytes, CRP, Albumine and fecal calprotectin and baseline variables like age, gender, treatment characteristics, anatomic distribution and duration of disease.

Study description

Background summary

Adalimumab (Humira) is a monoclonal antibody that binds with tumor necrosis factor (TNF). Treatment consists of a 40 mg subcutaneous injection every other week. Adalimumab treatment is effective for inducing clinical remission in patients with Crohn's disease (CD) and ulcerative colitis (UC) An optimal serum ADA concentration window of 5-12 ug/ml has been proposed. Besides efficacy

concerns with low serum trough concentrations (the serum concentration just before the next injection), hypothetically supra-therapeutic serum levels may lead to safety concerns and side effects.
Paradoxically, patients treated with anti-TNF agents can experience other immune mediated inflammatory disorders such as inflammatory skin lesions and joint problems. Our clinical observation is that patients with supratherapeutic levels often experience side effects, such as skin lesions, artralgia and fatigue, which sometimes disappear after dose de-escalation. However, the association of side effects of ADA with high ADA serum concentrations has not been prospectively studied until date.

Study objective

Primary Objective
The primary objective of this study is to assess whether high ADA serum levels lead to more side effects compared to therapeutic ADA levels in CD and UC patients who are in clinical and biochemical remission.

Secondary Objective
The secondary objective is to describe the variation of ADA serum levels and fecal Calprotectin levels at screening in IBD patients in clinical remission.

Study design

The design of the study is a single-centre, prospective, cross-sectional study. The study is an observational study with non-invasive measurements. The setting will be out-patients visiting the out-patient clinic of the Academic Medical Center in Amsterdam.

Study burden and risks

Participation in this trial could result in one extra hospital visit if it is not feasible to combine this study with a scheduled visit. At visit subject wil be asked to complete a questionnaire and blood (6x 5ml tubes) and fecal sample will be collected.

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

IBD diagnose, in clinical and biochemical remission on adalimumab maintenance therapy

Exclusion criteria

-biochemical parameters contradicting complete remission. (high fecal calprotectin and CRP)
-conditions or co-morbidities which could potentially cause symptoms like, fatigue, joint pain and skin lesions (such as infectious disease, arthritis, malignancy or pregnancy).
-detectable anti-bodies to adalimumab,

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	18-07-2014
Application type:	First submission
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
CCMO	NL48827.018.14