Anti -Infliximab or -Adalimumab Immunization (the AIAI study)

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• To determine the immunogenicity prediction in PBMCs of patients treated with Infliximab and Adalimumab using the MAPPs assay.• To investigate whether the peptides presented upon in vitro loading of Dendritic Cells are also presented in vivo after...

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

Summary

ID

NL-OMON42704

Source
ToetsingOnline

Brief title
AIAI

Condition

- Autoimmune disorders
- Joint disorders

Synonym
rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Novartis

Intervention

Keyword: anti-drug antibodies, biologicals, prediction immunigenicity, rheumatoid arthritis

Outcome measures

Primary outcome

determination of antibodies against biologicals after 3 months.

Secondary outcome

determination of peptides in vivo after dosing of biologicals.

Study description

Background summary

The introduction of biopharmaceutical (BP) has been critical step forward in care for RA and 9 BP are now licensed for the treatment of RA. In spite of this progress, failure of response to BP is frequent and in most of the registries, less than 50% of patients are still under drug at 5 years. These failures may be primary or secondary failures. The fact is that the low level of response becomes insufficient compared to the expectations. One of the main potential causes of these failures of BP therapy response is the development of ADAb in some patients. ADAb may decrease the efficacy BP's by neutralizing them or modifying their clearance and they may be associated with BP-specific hypersensitivity reactions. The prediction, prevention and cure of anti-drug (AD) immunization are thus major goals in BP development. In addition, many factors (patient-, disease- or product-related) may influence the potential risk of BP immunogenicity. Therefore, the immunogenic potential of BPs can only be definitively assessed in human studies.

Study objective

• To determine the immunogenicity prediction in PBMCs of patients treated with Infliximab and Adalimumab using the MAPPs assay.
• To investigate whether the peptides presented upon in vitro loading of Dendritic Cells are also presented in vivo after dosing.

Study design

After signing informed consent, the patient will be screened for inclusion. If no screening failure occurs, after the baseline blood sampling, a second blood

draw will be performed after >3 months after the first dose of Adalimumab or Infliximab, and if possible between 24-72 hours after the latest dosing.

Study burden and risks

burden: 2 x extra blood sampling. Blood sampling will be done during standard care.
risk: side effects of blood sampling: pain during blood collection, bruising or bleeding, faint.

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

- 18 years of age or older
- RA according to 2010 ACR/EULAR criteria
- Patients for whom the treating rheumatologist has decided to prescribe in routine practice in accordance with prescription guidelines for commercial use and independently from study entry:
o Adalimumab or Infliximab in first line.
o Adalimumab or Infliximab after failure with other anti-TNF therapy.
- Patient agreed to participate in the study by signing an informed consent.

Exclusion criteria

- Patient under any administrative or legal supervision.
- Patients who were previously treated with Adalimumab or Infliximab.
- Impossibility to meet specific protocol requirements (e.g. blood sampling).
- Uncooperative patients or any condition that could make the patient potentially non-compliant to the study procedures.
- Pregnant or breast-feeding women.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-01-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL53895.058.15