In-vitro whole blood pharmacodynamics in rheumatoid arthritis

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We would like to investigate if we can develop a biomarker test that enables us to identify patients that will respond to therapy or not before start of therapy. Research will be focused on ex vivo studies with whole blood that will be treated in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38292

Source
ToetsingOnline

Brief title
In-vitro pharmacodynamics in rheumatoid arthritis

Condition

- Joint disorders

Synonym
arthritis, chronic joint inflammation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: genomics, pharmacology, rheumatoid arthritis, whole blood

Outcome measures

Primary outcome

The most important outcome will be the interindividual differences in gene

expression levels based on the ratio between untreated (t=0) and 24h/48h after

in vitro addition of the specific drug to the whole blood.

Secondary outcome

n/a

Study description

Background summary

Rheumatoid arthritis is a heterogenous disease, shown by differences in disease activity, disease types and therapy responsiveness between patients. For anti-TNF treatment, one of the most succesfull therapies in RA, 30% of patients show no clinical improvement (ACR20). Similar findings are found for other biological therapies. Up until now it is not known beforehand what patients will benefit from therapy or not. As a result, some patients get unneccessary expensive treatment without gaining improvement and other patients are excluded from potential beneficial therapy.

Study objective

We would like to investigate if we can develop a biomarker test that enables us to identify patients that will respond to therapy or not before start of therapy. Research will be focused on ex vivo studies with whole blood that will be treated in vitro with the specific drug. By gene expression profiling we aim to investigate the in vitro response to the drug and translate this to the farmacological differences that are seen between patients. This research could lead to the identification of biomarkers that predict the responsiveness of an indivual to certain therapy.

Study design

VUmc will develop an in vitro assay to determine the response of an individual RA patient to certain biological therapy. Whole blood of RA patients will be treated in vitro with a specific drug after which the cells will be isolated and the mRNA expression profile will be determined.
The following conditions will be used:
1. Untreated, t=0h, t=24h and t=48h
2. Drug A, t=0h, t=24h, t=48h

Study burden and risks

The research will be performed with whole blood from RA patients that will be drawn when the patients are in the clinic for blood collection anyway. Therefore inconvenience is minimal.

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

Patients with rheumatoid arthritis that have active disease and are selected to start with biological therapy (i.e. anti-TNF (etanercept, infliximab and adalimumab), rituximab, tocilizumab, abatacept or anakinra)

Exclusion criteria

Patients that have no active disease

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-11-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	27-04-2011
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	06-12-2011
Application type:	Amendment

Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	25-09-2012
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL35405.048.11