Long term effectiveness of COBRA-light and COBRA treatment in early rheumatoid arthritis

Published: 11-12-2012
Last updated: 26-04-2024

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

Summary

ID

NL-OMON39638

Source
ToetsingOnline

Brief title
COBRA-light four year extension study

Condition

- Autoimmune disorders
- Joint disorders

Synonym
Rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: COBRA (light) treatment, early RA, follow-up study, long term effectiveness

Outcome measures

Primary outcome

The most important parameters of the follow-up study are the status of disease activity (DAS44 score), functional capacity (HAQ score) and radiological progression (Sharp/van der Heijde score) per treatment group after 48 months. The results of both treatment groups will be compared with each other. In addition, the average disease activity, functional capacity and radiological progression of the past 48 months will be calculated and compared between treatment both groups.

Secondary outcome

Secondary study parameters of the study are the level of improvement of the patients (ACR response score), RA medication use, adverse events and potential additional medication use and the Charlson Comorbidity Index (CCI).

Study description

Background summary

Recent research showed that COBRA-light therapy is clinically non-inferior to standard COBRA therapy: both strategies effectively lower disease activity after six months treatment in early, active RA patients. As it is of major importance to investigate the long term effects of the new treatment, we would like to initiate a new study to investigate the effects of the COBRA-light treatment after four years follow-up.

Study objective

The follow-up study has two main research questions:

o Is the treatment of early RA according to the COBRA-light schedule as effective (based on DAS44 score, ACR/EULAR remission criteria, HAQ score and the Sharp/van der Heijde score) as standard COBRA therapy after four years?
o What is the course of the disease in this group of early RA patients, who were intensively treated according to modern combination therapies during the past four years?

Study design

The follow-up study is an observational study, consisting of one visit per patient. The measurements will, on average, be performed four years after inclusion.

Study burden and risks

The follow-up study consists of one visit per patient, which will take about two to three hours per patient. The next measurements will be performed during this measure moment: a short interview, a physical examination (among others: height and weight, waist-hip-circumference, examination of the joints, bioelectrical impedance analysis and an ultrasound examination of the carotid arteries) and the patient will be asked to fill out eight questionnaires. In addition, blood will be collected at the laboratory, an electrocardiogram will be made, and X-ray photo*s and DXA-scans will be made at the Radiology department.
The risks of the follow-up study consist of the (usual) risk at blood collection and an additional radiation burden, as patients participating in this study are exposed to additional X-rays, compared to regular health care, when the whole-body DXA-scan is performed. The amount of extra radiation to which the patient is exposed during this measurement is 0.01 mSv, which is lower than the amount of additional radiation that is allowed in our country.

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

All patients who participated in the COBRA-light-study (and who started with the therapy).

Exclusion criteria

Patients who did not start with the COBRA therapy

Study design

Design

Study phase:	4
Study type:	Observational invasive
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):	04-04-2013
Enrollment:	162
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2013
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
CCMO	NL42005.029.12