Treatment in the Rotterdam Early Arthritis CoHort

Published: 27-04-2007
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5. Study objective(s) and hypothesis:The aim of this study is to assess the value of early, intensive and efficient treatment of patients with recent acquired arthritis, in preventing progression into destructive RA

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON38216

Source
ToetsingOnline

Brief title
tREACH

Condition

- Joint disorders

Synonym
Rheumatoid Arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Early, efficient, Intensive, Rheumatoid Arthritis, treatment

Outcome measures

Primary outcome

•Primary endpoints: Disease activity:

Disease activity:

Area under the curve (AUC) DAS

Functionality:

AUC HAQ during 1 year of therapy

Joint damage:

Radiologic progression

Secondary outcome

•Secondary endpoints:

Absence of arthritis

WHO/ILAR Core-set

Self-assessed disease activity (RADAI)

Cost (medical direct/indirect)

Mediation reduction in time

Study description

Background summary

5. Study objective(s) and hypothesis:

The aim of this study is to assess the value of early, intensive and efficient treatment of patients with recent acquired arthritis, in preventing progression into destructive RA

6. Study background/rationale:

Recognition of rheumatoid arthritis (RA) early in the disease course is becoming increasingly important since early and intensive treatment has shown to prevent joint damage, achieves higher remission rates, and preserves function and work participation. However, the obstacle of RA is early recognition since the early phase of RA, the disease has a atypical presentation. Furthermore, 60% of the patients with recent acquired arthritis are self-limiting. The most effective therapies of RA are also the ones with the highest risk of toxicity and/or infections. Consequently, for efficient treatment it is important to pick only those patients who will develop RA.
In this trial the value of early, intensive and efficient treatment of patients with recent acquired arthritis will be assessed, in preventing the progress to destructive RA.

Early treatment will be derived by recruiting patients directly from the general practitioner via the *Rotterdam Early Arthritis Cohort* (REACH). This cohort includes patients who are 16 years and older with signs of inflammatory joints existing less than one year.
The assessment of Intensive treatment will be accomplished by randomizing patients in three treatment strategies of DMARD combination therapy which has been shown to be effective in patients with established RA. The treatment is aimed to achieve *no arthritis* in all subgroups. Patients will be monitored every 3 months. If initial therapy fails (DAS > 2.4) the next step in the treatment strategy will be HUMIRA. If patients have a low disease activity (DAS < 2.4) at two visits in row (> 6 months) medication will be tapered. (see attachment organization chart)

Efficient treatment will be accomplished by treating patients stratified by their chance to develop RA. This chance will be calculated by using a prediction rule which was developed based on probability of RA.[1] Patients with a chance of more than 70% to develop a RA will be treated more intensively than patients with a 50% chance or less. The attached abstract shows that this efficient manner of treatment guided by a prediction rule, will keep the over- and under treatment of patients to a minimum.[see attached abstract]

Study objective

5. Study objective(s) and hypothesis:

The aim of this study is to assess the value of early, intensive and efficient treatment of patients with recent acquired arthritis, in preventing progression into destructive RA

Study design

7. Study design:
• prospective
• parallel
• multi-center

If study is multicenter, attach list of all participating sites and names of local investigators:
Erasmus MC
SFG
Maasstad
AsZ
Vlietland
Zorgsaam
Ziekenhuis walcheren
Oosterschelde ziekenhuis

• Single-blind
• Randomized

Intervention

17. Dose/regimen:
Per subgroup patients will be randomized in three treatment strategies of DMARD combination therapy. Treatment strategies are aimed to achieve *no arthritis* in all subgroups. Patients will be monitored every 3 months. If initial therapy succeeds, medication will be reduced, if initial therapy fails (DAS > 2.4) the next step in the treatment strategy will be initiated. If patient has a good response to the administered medication, an attempt is made to reduce the dose of the drug(s).

Subgroup 1 (high probability (> 70%; RA group)
a. Methotrexate in combination with a cumulative high dose corticosteroids
b. Combination of MTX, SSZ, HCQ and single bridging i.m. corticosteroids
c. Combination of MTX, SSZ, HCQ and a cumulative high dose corticosteroids

Subgroup 2 (intermediate probability > 34% and < 70%)

a. Methotrexate
b. Plaquenil
b. Corticosteroids
Initial dose:
MTX 25 mg/ week
SSZ 2 dd 1 gr
HCQ 2 dd 200 mg
Prednison 1 dd 10 mg
Enbrel

Study burden and risks

Patients are threated confirm existing medication protocols. The extra Burden consist of time necessairy for filling out questionaires

Patients tapering down methotrexate and anti-TNF will be asked permission to undergo max 6 ultrasonographic examinations of the joints (30 min/examination)

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

dr. Molewaterplein 50
Rotterdam 3015 GE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

dr. Molewaterplein 50
Rotterdam 3015 GE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

To be able te sign informed consent
-Patients must meet the inclusion criteria for the REACH. That is: object arthritis, pain and or limitation of motion in 2 or more joints in combination with 2 of the following criteria: morningstiffness, tangential pain in MTP/MCP, pos fam anamneses, symm presentation, unexplained fatigue.

Exclusion criteria

Complaints> 1 year by trauma or overload, no possibility to communicate, definitive diagn of gout, infectious arthritis or systematic disease, use of antirheumatic preparates before start study, contra indication for medication.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-07-2007
Enrollment:	1080

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Enbrel
Generic name:	Ethanercept
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Hydroxychloroquine
Generic name:	Plaquenil
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Methotrexate
Generic name:	Lederthrexate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Prednison
Generic name:	Prednisolon
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Sulfasalazine
Generic name:	Salazopyrine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-04-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-05-2007
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-12-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-01-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-02-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-07-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-07-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2006-005771-18-NL
CCMO	NL14580.078.06