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Treatment in the Rotterdam Early Arthritis CoHort

Submission date	Recruitment status
23/08/2007	No longer recruiting
Registration date	**Overall study status**
23/08/2007	Completed
Last Edited	**Condition category**
21/10/2024	Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof J.M.W. Hazes

Contact details
Department of Rheumatology Ee965
Rotterdam
Netherlands
3000 WB
+31 (0)10 703 4602
j.hazes@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR1019

Study information

Scientific Title
Treatment in the Rotterdam Early Arthritis CoHort: a stratified, randomised clinical trial in patients with recent-onset arthritis

Acronym
(T)REACH

Study objectives
In each stratum of probability there is a clinically and statistically significant difference in the functional ability and disease activity score over time (area under the curve) and progression of radiological joint damage after one year of follow-up in recent-onset arthritic patients who were having induction treatment with divergent intensity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee Erasmus University Rotterdam gave approval

Study design
Multicentre randomised single-centre parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at: http://www.erasmusmc.nl/reumatologie/onderzoek/TREACH/

Health condition(s) or problem(s) studied
Recent onset arthritis, rheumatoid arthritis

Interventions
Three monthly evaluations of disease activity score and safety. Medication adjustments by protocol, based on Disease Activity Score (DAS) calculations. If DAS is less than 2.4, medication will be switched to more intensive treatment including biologicals (initial biological will be etanersept). If DAS less than 1.6 is achieved for at least six months, patients will start to taper and finally stop all medication.

Induction therapy for the three strata will be:
1. High probability (HP)-group:
1.1. Methotrexate (MTX) + Sulfasalazine (SSZ) + Hydroxychloroquine (HCQ) + one single dose corticosteroid intramuscular

1.2. MTX + SSZ + HCQ + prednisone
1.3. MTX + prednisone
2. Intermediate Probability (IP)-group:
2.1. MTX
2.2. HCQ
2.3. Prednisone
3. Low Probability (LP)-group:
3.1. Naproxen
3.2. HCQ
3.3. One single dose corticosteroids intramuscular

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methotrexate, sulfasalazine, hydroxychloroquine, prednisone, naproxen

Primary outcome measure
1. Functional ability as measured by HAQ and DAS over time (area under the curve), assessed every 3 months
2. Progression of radiological joint damage as measured by Sharp/van der Heijde score, assessed every 6 months

Secondary outcome measures
1. American College of Rheumatology (ACR) arthritis core-set, assessed every 3 months
2. Quality of Life, as measured with 36-item Short Form (SF-36), European Quality of Life scale (EuroQoL), assessed every 3 months
3. Costs

Overall study start date
01/07/2007

Completion date
01/07/2011

Eligibility

Key inclusion criteria
1. Participant of the REACH cohort (patients with inflammatory joint complaints less then one year)
2. All patients must at least have one (out of 66) swollen joint

Added 23/04/2009:
3. Aged 18 years or older, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
810

Total final enrolment
568

Key exclusion criteria
1. Definite diagnosis of crystal arthropathy, (post) infective arthritis or autoimmune rheumatic disorder
2. Previous therapy with disease modifying anti-rheumatic drugs (DMARDs) or corticosteroids
3. Pregnancy or wish to become pregnant during the study, or childbearing potential without adequate contraception
4. Concomitant treatment with an other experimental drug
5. History or presence of malignancy within the last five years
6. Elevated hepatic enzyme levels (aspartate aminotransferase [ASAT], alanine aminotransferase [ALAT] greater than two times normal value)
7. Thrombopoenia less than 150 x 10^9/l
8. Leucopoenia less than 3.0 x 10^9/l
9. Serum creatinine level greater than 150 umol/l

Date of first enrolment
01/07/2007

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3000 WB

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
Department of Rheumatology
Rotterdam
Netherlands
3000 CA

Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/content/englishindex.htm

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Wyeth Pharmaceutical B.V. (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol	protocol	18/06			

article		/2009		Yes	No
Results article	results	01/10 /2012		Yes	No
Results article	1-year results	01/07 /2014		Yes	No
Results article	results	01/12 /2016		Yes	No
Results article	results on association between DNA methylation and methotrexate response	26/06 /2019	28/06 /2019	Yes	No
Results article	results	01/09 /2018	12/08 /2019	Yes	No
Results article	results on correlation between risk factors and clinical course	23/01 /2021	25/01 /2021	Yes	No
Results article	results on cost utility	16/03 /2021	17/03 /2021	Yes	No
Results article	results on DMARD-free remission	05/08 /2021	06/08 /2021	Yes	No
Results article	Combining patient-reported outcome measures to screen for active disease in rheumatoid arthritis and psoriatic arthritis	18/10 /2024	21/10 /2024	Yes	No