Treatment in the Rotterdam Early Arthritis CoHort

Submission date Recruitment status Prospectively registered 23/08/2007 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 23/08/2007 Completed [X] Results [] Individual participant data **Last Edited** Condition category 21/10/2024 Musculoskeletal Diseases

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 vear)
- 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 $150 \times 10^9/l$
- 8. Leucopoenia less than $3.0 \times 10^9/l$
- 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 Details

Protocol protocol

Date Date Peer Patientcreated added reviewed? facing? 18/06

<u>article</u>		/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