Treatment in the Rotterdam Early Arthritis CoHort

Submission date	Recruitment status No longer recruiting	Prospectively registeredProtocol			
23/08/2007					
Registration date	Overall study status	Statistical analysis plan			
23/08/2007	Completed	[X] Results			
Last Edited 21/10/2024	Condition category Musculoskeletal Diseases	Individual participant data			
Z 1/ 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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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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. HCO
- 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(s)

- 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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

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)

ROR

https://ror.org/018906e22

Funder(s)

Funder type

Industry

Funder Name

Wyeth Pharmaceutical B.V. (Netherlands)

Results and Publications

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?
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
Protocol article	protocol	18/06 /2009		Yes	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes