

Treatment in the Rotterdam Early Arthritis CoHort

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| Submission date 23/08/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 23/08/2007 | Overall study status Completed | <input checked="" type="checkbox"/> Protocol |
| Last Edited 21/10/2024 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 etanercept). 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(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 than 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

All

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. Thrombopenia less than $150 \times 10^9/l$
8. Leucopenia 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 |