# The RAINBOW study: Rheumatoid Arthritis ImplemeNtation of Biological dose Optimization in real World

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Suspended |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22185

**Source**
NTR

**Brief title**
RAINBOW

**Health condition**

Rheumatoid Arthritis (RA)

### Sponsors and support

**Primary sponsor:** This is an investigator-initiated study, funded by the Sint Maartenskliniek
**Source(s) of monetary or material Support:** There are no external funders

### Intervention

### Outcome measures

**Primary outcome**

• bDMARD use (amount prescribed by rheumatologist)

• Disease activity (RAPID3 questionnaire)

We want to investigate whether the extended implementation strategy is superior to the main strategy. This is the case if the following combined objective is met: the extended strategy reduces bDMARD use while being non-inferior on disease activity. Since testing for non-inferiority on disease activity is only relevant when the extended strategy proves to be effective in reducing bDMARD use, we will perform a fixed sequence testing procedure. First, we will test the difference between groups on bDMARD use. When the extended strategy has a significantly different effect on bDMARD use compared to the main strategy, we will continue to test for non-inferiority on disease activity. When the extended strategy does not have a significantly different effect on bDMARD use, we will not test disease activity.

Thus we will first test

H0= The addition of treatment advice to the main strategy (extended strategy) has the same effect on mean bDMARD use as the main strategy at 18 months.

H1 = the addition of treatment advice to the main strategy (extended strategy) has a different effect than the main strategy on mean bDMARD use at 18 months.

If this test is statistically significant, we will test:

H0'= The addition of treatment advice is not non-inferior with regard to disease activity at 18 month.

H1'= The addition of treatment advice is non-inferior with regard to disease activity at 18 months.

The trial (and the extended implementation strategy) is considered a success if the first test shows that the extended program statistically significantly reduces bDMARD use compared to the main strategy and it is non-inferior on disease activity. However, due to the two-sided testing in the first test, we will also be able to conclude that the extended strategy statistically significantly increases bDMARD combined or not with non-inferiority on disease activity.

**Secondary outcome**

• Quality of Life (EQ5D-5L)

• bDMARD use (amount from declaration data)

• bDMARD use (amount reported by patient)

• Disease activity (DAS28/CDAI/SDAI)

• Acute phase reactants (ESR, CRP)

• Concomitant medication

# Study description

### Background summary

Country: Hospitals and patients will be recruited in the Netherlands

### Study objective

We hypothesize that a multifaceted implementation strategy can stimulate the use of tight control and bDMARD dose optimization in clinical practice, measured by decreased bDMARD use and non-inferiority on disease activity at 18 months.

### Study design

Primary outcome measures

• bDMARD use (amount prescribed by rheumatologist)

Timepoints: Looking at dose and dosage adjustments during whole study period

• Disease activity (RAPID3 questionnaire)
Timepoints: study start, 9 months and 18 months.

Secondary outcome measures

• Quality of Life (EQ5D-5L)

Timepoints: study start, 9 months and 18 months.

• bDMARD use (amount from declaration data)
Timepoints: Looking at bDMARD use during study period

• bDMARD use (amount reported by patient)
Timepoints: study start, 9 months and 18 months.

• Disease activity (DAS28/CDAI/SDAI value reported in electronic health record)

Timepoints: study start and 18 months.

• Acute phase reactants (ESR and CRP values reported in electronic health record)

Timepoints: study start and 18 months.

• Concomitant medication reported in electronic health record

Timepoints: study start and 18 months.

**Intervention**

Participating hospitals will receive the developed implementation strategy that aims to improve tight control and disease activity guided bDMARD dose optimization The strategy consists of the following steps: 1) providing financial incentive for participation, 2) an inventory of the local situation, 3) education, 4) development of local protocols, 5) advice, 6) interim progress meeting 7) feedback and 8) decision support (treatment advice for the rheumatologist in the electronic health records of all bDMARD users, based on the local protocols).

We want to investigate whether the implementation strategy can improve bDMARD dose optimization. This is the case if the following combined objective is met: the strategy reduces bDMARD use while being non-inferior on disease activity. Since testing for non-inferiority on disease activity is only relevant when the strategy proves to be effective in reducing bDMARD use, we will perform a fixed sequence testing procedure. First, we will test the difference between before and after measurement on bDMARD use. When the strategy has a significant effect on bDMARD use, we will continue to test for non-inferiority on disease activity. When the strategy does not have a significant effect on bDMARD use, we will not test disease activity.

Thus we will first test
H0= The implementation strategy has no effect on mean bDMARD use at 18 months compared to mean bDMARD use at baseline.
H1 = the implementation strategy has a significant effect on mean bDMARD use at 18 months compared to mean bDMARD use at baseline.
If this test is statistically significant, we will test:
H0'= The implementation strategy increases the mean disease activity at 18 months, compared to mean disease activity at baseline (inferiority) using a pre-defined non-inferiority margin.
H1'= The implementation strategy does not increase the mean disease activity at 18 months, compared to mean disease activity at baseline (non-inferiority) using a pre-defined non-inferiority margin.

The trial is considered a success if the first test shows that the implementation strategy statistically significantly reduces bDMARD use and is non-inferior on disease activity. However, due to the two-sided testing in the first test, we will also be able to conclude that strategy statistically significantly increases bDMARD use combined or not with non-inferiority on disease activity.

# Contacts

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# Eligibility criteria

## Inclusion criteria

• Rheumatoid arthritis (clinical diagnosis of treating rheumatologist, fulfilled at any time point between start of the disease and inclusion) operationalized by DOT diagnosis 101.

• Being treated in a center in which the RAINBOW implementation project is starting

• Females and males ≥18 years and mentally competent

• Using a bDMARD (all dose/interval regimens, all background medication including sDMARDs and corticosteroids)

• Informed consent given

• Ability to measure the outcome of the study in this patient (e.g. life expectancy > 1,5 year, no planned relocation)

• Ability to read and communicate well in Dutch

### Exclusion criteria

None

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Suspended |
| Start date (anticipated): | 04-01-2016 |
| Enrollment: | 320 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

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|---|---|
| Date: | 12-10-2015 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL5354 |
| NTR-old | NTR5464 |
| CCMO | NL54695.091.15 |

# Study results