BeSt Treatment Strategies. A randomized clinical trial to test the effectiveness of different treatment-strategies in patients with early rheumatoid arthritis. Long term follow-up.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22114

Source
NTR

Brief title
BeSt

Health condition

All patients continue treatment according to the treatment group they were allocated to at the beginning of the BeSt trial. All treatment adjustments will continue to be based on threemonthly DAS measurements, aiming at DAS =<2.4 (or <1.6 before medication may be stopped altogether).

Sponsors and support

Primary sponsor: Schering-Plough
Centocor
Source(s) of monetary or material Support: orignial BeSt trial funded by Dutch College of Health Insurance Companies

Intervention

Outcome measures

Primary outcome

1. Functional ability as measured by HAQ;

2. Radiological damage as measured by Sharp/van der Heijde score of hands and feet;

3. Side effects and extra-articular manifestations (as reported and as monitored through laboratory assessments, X-rays, DEXAs).

Secondary outcome

1. Quality of life;

2. Utilities;

3. Work participation;

4. Costs.

Study description

Background summary

N/A

Study objective

1. Earlier identified differences in functional ability and radiological damage progression are maintained in the next ten years;
2. Early suppression of disease activity results in long term improvement in functional ability and suppression of joint damage progression;
3. Clinical remission can be maintained after discontinuation of all antirheumatic drugs in identifiable patients;
4. There is a clinically and statistically significant difference in extra-articular manifestations and side effects of medication between patients in the various treatment groups.

Intervention

Continued treatment with established antirheumatic drugs according to accepted treatment

strategies, with threemonthly treatment adjustments dictated by the height of the DAS: if DAS>2.4, than medication will be increased or changed, if, for at least 6 months DAS <2.4, medication will be tapered, if, for at least 6 months DAS <1.6, medication will be stopped.

Contacts

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Eligibility criteria

Inclusion criteria

All patients who completed participation in the first 2 years of BeSt.

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2004
Enrollment:	500
Type:	Actual

Ethics review

Positive opinion

Date:	08-09-2005
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	NL227
NTR-old	NTR265

Register	ID
Other	: N/A
ISRCTN	Follow-up of ISRCTN32675862

Study results

Summary results
N/A