

Treatment strategies for Rheumatoid Arthritis (BeSt - BehandelStrategieën in Reumatoïde Artritis)

Submission date
20/12/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
20/12/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
22/06/2010

Condition category
Musculoskeletal Diseases

☐ Individual participant data

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

1

Study information

Scientific Title

Acronym

BeSt

Study objectives

There is a clinically and statistically significant difference in functional ability and progression of radiological joint damage after two years of follow-up in patients with early Rheumatoid Arthritis (RA) who receive initial combination therapy, combination therapy after failure of optimal treatment with Methotrexate (MTX), or initial therapy with a Tumour Necrosis Factor (TNF)alpha-blocking agent, compared to those receiving combination therapy after intensive treatment with the most effective consecutive single Disease Modifying Anti-Rheumatic Drugs (DMARDs).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The medical ethics committee at each participating centre approved the study protocol, and all patients gave written informed consent before study inclusion.

Study design

Randomised Controlled Trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

Treatment of RA with established anti-rheumatic medication according to four different, accepted strategies:

Group one: sequential monotherapy
Group two: step-up combination therapy
Group three: initial combination therapy with tapered high-dose prednisone
Group four: initial combination therapy with infliximab

All medication steps are dictated by a strategy specific pharmacoprotocol. Treatment adjustments made on the basis of three monthly measurements of Disease Activity Score (DAS) (or on occurrence of side effects). All patients are treated aggressively, aiming at low disease activity, based on three monthly calculations of a DAS.

In all four strategy groups the medication is increased or altered if the DAS is 2.4 or higher, or, if the DAS is less than 2.4 for at least six months, tapered to a single drug maintenance dose. A trained research nurse who remains blinded for the treatment that patients receive calculates the DAS.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Methotrexate, infliximab, prednisone

Primary outcome measure

After two years of follow-up:

1. Functional ability as measured by HAQ (collected by blinded research nurse)
2. Joint damage on X-rays of hands and feet (Sharp/van der Heijde method, random in time, by two independent physicians, X-rays masked for center and patient identity)

Secondary outcome measures

1. Side effects
2. Quality of life
3. Utilities
4. Costs

Overall study start date

01/03/2000

Completion date

01/08/2004

Eligibility

Key inclusion criteria

1. Patients (18 years or older) with rheumatoid arthritis (American College of Rheumatology [ACR] 1987 criteria)
2. Diagnosis since less than two years
3. Previously untreated with DMARDs
4. With active disease (at least 6/66 swollen and at least 6/68 painful joints, and either

Erythrocyte Sedimentation Rate [ESR] 28 mm or more or Visual Analogue Scale [VAS] general well being (by patient) of 20 mm or more)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

508

Key exclusion criteria

1. Previous therapy with DMARDs except for hydroxychloroquine
2. Pregnancy or wish to become pregnant during the study, or childbearing potential without adequate contraception
3. Concomitant treatment with another experimental drug
4. History or presence of malignancy within the last five years
5. Bone marrow hypoplasia
6. Elevated hepatic enzyme levels (Aspartate Aminotransferase [ASAT], Alanine Aminotransferase [ALAT] greater than three times normal value)
7. Serum creatinine level greater than 150 umol/l or estimated creatinine clearance of less than 75 ml/min
8. Diabetes mellitus
9. Alcohol or drug abuse

Date of first enrolment

01/03/2000

Date of final enrolment

01/08/2004

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Center,
Leiden
Netherlands
2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details

Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type

University/education

Website

<http://www.lumc.nl/>

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Industry

Funder Name

Centocor (Netherlands)

Funder Name

Schering-Plough (Netherlands)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Dutch Health Care Insurance Board (CVZ, independent government organisation) (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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/03/2007		Yes	No
Results article	results	01/09/2007		Yes	No
Results article	results	01/07/2010		Yes	No