Switching treatment from innovator etanercept (Enbrel) to etanercept biosimilar (Benepali) in patients with a rheumatic disease in daily clinical care.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21708

Source
Nationaal Trial Register

Brief title
BIO-SPAN

Health condition

Rheumatic diseases
Biosimilar
Persistence

Sponsors and support

Primary sponsor: Sint Maartenskliniek Nijmegen
Source(s) of monetary or material Support: Biogen

Intervention

Outcome measures

Primary outcome

Difference in 6-months treatment persistence rate between Benepali in the switch cohort and Enbrel in the historical cohort.

Secondary outcome

- To compare persistence of treatment with Benepali at 6 months of follow-up between the patient group that was randomly asked to fill in questionnaires at baseline and the patient group that was not.

- To compare initial beliefs about biosimilar treatment (measured with CEQ, SETS and BMQ) between patients and rheumatologists.

- To compare efficacy (difference in mean DAS28-CRP (for RA and PsA) and mean BASDAI (for SpA) between baseline (before first biosimilar injection) and at 6 and 12 months of treatment.

- To evaluate safety (adverse events (AEs) and serious adverse events (SAEs)) during the follow-up period.

- To assess whether patients' and rheumatologists' characteristics and initial beliefs are associated with persistence of treatment with Benepali at 6 months of follow-up.

Study description

Background summary

Possible determinants of the 6-months persistence of treatment with a biosimilar in patients with a rheumatic disease will be investigated. Secondary endpoints include efficacy and safety outcomes during the 1 year follow-up period.

Study objective

To investigate the impact of an open label non-mandatory switching strategy from Enbrel to Benepali on drug survival, effectiveness and safety in a controlled cohort study of RA, PsA and SpA patients in daily practice.

Study design

Data will be recorded at baseline and after 6 and 12 months (+/- 2 months) of treatment.

Intervention

Patients who switch treatment from Enbrel to Benepali will be asked to participate in this study. At baseline, patient and rheumatologist characteristics will be collected. Half of the

included patients will randomly be asked to fill in validated questionnaires before the administration of the first Benepali injection (CEQ, SETS, BMQ, ASES). Rheumatologists will be asked to fill in the adapted CEQ, SETS and BMQ and perform an Implicit Association Test. Data on efficacy and safety will be obtained during the outpatient clinical visits performed in usual care at baseline and after 6 and 12 months of follow-up.

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Eligibility criteria

Inclusion criteria

- Switched from Enbrel to Benepali in daily clinical practice in the Sint Maartenskliniek

- Older than 18 years of age

- Ability to read and communicate well in Dutch

- Informed consent

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2016
Enrollment:	500
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	15-06-2016
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	NL5747
NTR-old	NTR5901
Other	Submitted to CMO: not WMO liable : 2016-2612

Study results

Summary results
https://pubmed.ncbi.nlm.nih.gov/29609207/