Orencia home infusion.

No registrations found.

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

Summary

ID

NL-OMON23292

Source
NTR

Health condition

Rheumatoid Arthritis
Orencia
Home infusion / thuis infusie

Sponsors and support

Primary sponsor: Atrium MC Heerlen
Source(s) of monetary or material Support: Bristol-Myers Squibb B.V.

Intervention

Outcome measures

Primary outcome

Satisfaction of all parties (incl. patients) measured with questionnaires during month 1, 3 and 6.

Secondary outcome

1. Preparation Orencia (experience is documented in the patientbook every visit, the book is collected at the end of the visit);

2. No logistic problems (logistics are monitored by Medizorg every visit);

3. Cost aspect (costs are documented by Medizorg for every visit).

Objectives focus only on the location of the treatment.

Study description

Background summary

This study evaluates if it possible en desirable to move the Orencia treatement from the hospital to the patients home.
A total of 10 patients will be enrolled before the end of the year. Those patients will be treated at home with Orencia for 6 months. Before a patient can be treated at home patients will receive two infusions in the hospital. During month 1, 3 and 6 questionnaires are completed to monitor the satisfaction of the participants.

Study objective

Is it possible / desirable to move Orencia treatment from the hospital to the home situation?

Study design

6 months.

Intervention

Treatment is moved from the hospital to the home situation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18 years or older;

2. Moderate / severe RA;

3. MTX or TNF-alpha Inadequate responders;

4. At least two treatments with Orencia received in hospital;

5. Working phone available at patients home;

6. GP informed about participation in trial;

7. Patient has a clean and working refridgerator and a clean space to prepare Orencia;

8. Patient signed Informed Consent.

Exclusion criteria

1. Patient showed adverse events or infusional reaction while treated with Orencia in the hospital;

2. Patient has a cardiovascular problem or an uncontrolled infection;

3. The patient is pregnant or breast feeding;

4. The patient shows a hypersensitivity reaction to Orencia;

5. The patients history contains an analphylactic reaction or a significant allergic reaction;

6. The pation is treated with a biological DMARD;

7. The patient was vaccinated with a live vaccine in the 3 months previous to Orencia treatment;

8. The patients has a poistive TB screening and is not accurately treated;

9. The patient is treated for other indications then specified in the SmPC.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-09-2010
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-09-2010
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	NL2445
NTR-old	NTR2562
Other	Bristol-Myers Squibb BV : IM101-223
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A