(Cost-)effectiveness of electronic drug monitoring feedback in order to decrease non-adherence in RA-patients starting with biological DMARD - A randomised clinical trial at Reade

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To determine if electronic drug monitoring adherence feedback in standard care for patients with rheumatoid arthritis starting with a new biological DMARD is effective on medication adherence compared to a usual care group. The second objective is...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON42203

Source
ToetsingOnline

Brief title
Electronic monitoring feedback of patient*s adherence in rheumatology

Condition

- Joint disorders

Synonym
Rheumatoid Arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: Reade

Intervention

Keyword: Adherence/compliance, Biological/biological DMARD, Medication Event Monitoring System (MEMS), Rheumatoid Arthritis

Outcome measures

Primary outcome

The primary outcome measure will be the difference in proportion of non-adherence patients (less than 80% medication adherence) after 1 year between the intervention group and in the usual care control group assessed with the validated compliance questionnaire on rheumatology (CQR) and pharmacy refill data.

Secondary outcome

Secondary outcomes will be time to low disease activity and remission, serum trough levels (optional) and proportion of switching patients to another biological and mean disease activity after 1 year. Finally an economic evaluation of the possible added value of electronic drug monitor feedback compared with usual care will be done.

Study description

Background summary

To reduce disease activity and ultimately limit the joint damage as much as possible, DMARD-therapy (adequately taken by the patient) is warranted in the early stage of RA. Interventions to improve adherence are therefore necessary to reduce undesirable effects of non-adherence on health and medication costs.

The usage of drug monitoring devices (like Medication Event Monitoring System (MEMS*)) combined with personal feedback regarding medication behavior has proven in other diseases like HIV to be an effective strategy to improve adherence and therefore clinical outcome, decrease drug changes and drug use. Although these studies suggest that electronic drug monitor feedback might have the potential to prevent unnecessary treatment escalation in rheumatoid arthritis patients with poor adherence, empirical evidence to prove this drug-/cost saving potential is lacking. Implementing electronic monitoring feedback in RA might result in a cost effective strategy to reach earlier low disease activity and a prolonged persistence with current biological DMARDs.

Study objective

To determine if electronic drug monitoring adherence feedback in standard care for patients with rheumatoid arthritis starting with a new biological DMARD is effective on medication adherence compared to a usual care group. The second objective is to examine the effect of the intervention on costs and time with high disease activity.

Study design

Randomised, open clinical trial comparing electronic drug monitoring feedback with standard care.

Intervention

Patients in the intervention group receive their medication during 1 year in an electronic device. Before each regular (3-monthly) consult to the rheumatologist, patients medication adherence will be assessed by reading out the electronic device and in case of non-adherence (<80% adherence) possible barriers to medication intake will be discussed with the trained researcher/ -assistant on a semi-structured way. Patients in the control group will receive standard care (an interview with the pharmacy consultant without electronic drug monitor feedback).

Study burden and risks

Most patients are already invited for an interview about their medication use, assessment of the disease activity and blood sampling prior to their regular visit to the rheumatologist. The interview about patients medication is an excellent moment for introducing, reading out and discussing the electronic devices and their reports in this study. Electronic drug monitor feedback will be combined with the assessment of patient*s actual medication use. One session takes approximately 20-60 minutes each and is planned before each consult to the rheumatologist (after 3,6,9 and 12 months). Participating in this study needs just a little extra effort from the patient. The intervention program

does not constitute a risk for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosed with RA (2010 ARA criteria or clinical judgment by a rheumatologist)
Initiating a new (subcutaneously administered) bDMARD
>18 years
Sufficient ability to understand Dutch
Be able to be followed for 12 months (life expectancy)

Exclusion criteria

Large cognitive limitations
Assistance in taking drugs (e.g. home care)
Included in another randomised controlled trial

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2016
Enrollment:	227
Type:	Actual

Ethics review

Approved WMO

Date:	17-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL51522.048.14