Effectiveness and cost-utility of telemonitoring lab results and e-consultations in rheumatoïd artritis.

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The primary objective of the JOINT Monitoring study is to assess the impact of telemonitoring on the effects, measured in PROMS, and the costs considering a societal perspective, in Rheumatoid Arthritis patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON52237

Source
ToetsingOnline

Brief title
Joint Monitoring

Condition

- Autoimmune disorders

Synonym
Rheumatoïd arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Maasstad ziekenhuis

Intervention

Keyword: CEA, E-health, Home health monitoring, Lab results, Lancet, Rheumatoïd artritis, Societal perspective, Telecare, Telehealth, Telemedicine, Utility

Outcome measures

Primary outcome

The main study parameters are the effects measured in Patient Reported

Outcomes, making use of the EQ-5D questionnaires and the societal costs

associated with the implementation of telemonitoring amongst RA patients.

Secondary outcome

N/A

Study description

Background summary

The conventional healthcare provision is shifting more and more from hospitals to the living room of RA patients in an attempt to improve the value of healthcare delivered to patients. As a result of COVID-19, the uptake of e-health and telecare has increased. E-health and telemonitoring are considered as promising methods to observe patients remotely, thereby easing the burden for patients and shifting to a patient-centered healthcare system. Furthermore, telemonitoring is expected to become part of the usual care delivered by hospitals. In the JOINT Monitoring study we will introduce telemonitoring by the remote controlling of essential laboratory results and performing e-consultations.

Study objective

The primary objective of the JOINT Monitoring study is to assess the impact of telemonitoring on the effects, measured in PROMS, and the costs considering a societal perspective, in Rheumatoid Arthritis patients.

Study design

In the JOINT Monitoring study, we will conduct a cost-effectiveness analysis considering a societal perspective. The research design following the

cost-effectiveness study, is a non-randomized control study that will be performed at the outpatient department of the Maasstad Hospital, the Albert Schweitzer Hospital and the Medisch Spectrum Twente. The follow-up period will be 12 months.

Intervention

Applying the use of lancets at home for the (tele)monitoring of the essential laboratory results and the e-consultation is the intervention. The intervention is the shift from blood sampling and consultation at the hospital site to the home of the patient.

Study burden and risks

We qualified the risk of this study based on the guideline by the NFU (Dutch Federation of University Medical Centers) about quality insurance in human research (*Kwaliteitsborging van mensgebonden onderzoek*). The NFU guideline states that the extent of risk has to be estimated by considering the additional risk of an intervention compared to standard treatment.

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

- Diagnosis of rheumatoid arthritis as stated by the rheumatologist;
- Reported Patient Reported Outcomes Measures;
- Minimum age of 18 years;
- Able to provide informed consent;
- Literacy in Dutch.

Exclusion criteria

- Arthritis other than rheumatoid arthritis;
- Unable to take blood samples via lancets.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2022
Enrollment:	142
Type:	Anticipated

Ethics review

Approved WMO Date:	22-04-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-06-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL77176.100.21