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Telemonitoring of patient administered score RAPID3 to deliver NICE compliant treatment in rheumatoid arthritis

Submission date
17/01/2019

Recruitment status
Suspended

Registration date
12/02/2019

Overall study status
Completed

Last Edited
08/07/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Rheumatoid arthritis (RA) causes multiple joints pain, swelling and stiffness but truly can affect the whole body. It affects nearly half a million people in the UK and about 21,000 people in the country develop RA every year. With the dramatic advances in the drug treatment, most RA patients should be able to achieve remission. However, this unprecedented opportunity is lost in at least 50% of patients due to the nationwide shortfalls in implementing the NICE recommended treat-to-target management of RA. Poorly treated RA patients suffer joint damage, disability, shortened life span, are at high risk of losing employment and cost the UK economy £2.4b annually. This situation can be prevented by advising treatment modification based on telemonitored RAPID3, a patient-administered measure of RA activity, instead of the current gold standard DAS28, which is administered face-to-face by a clinician. There is a significant correlation between DAS28 and the routine assessment of patient index data 3 (RAPID3) which is self-administered by patients by completing a questionnaire about their pain, function and overall global health. Unlike DAS28, RAPID3 does not require joint counts or a laboratory test. RAPID3 is demonstrated to be reliable and able to differentiate well between active and inactive disease. The aim of this study is to find out whether telemonitored RAPID3 is equivalent to face-to-face DAS28 scoring in advising treatment modification towards achieving treat-to-target goal in RA.

Who can participate?
Newly diagnosed RA patients aged 18 or above seen in the rheumatology clinics at the Royal National Orthopaedic Hospital

What does the study involve?
Participants are randomly allocated to either telemonitored RAPID3 or clinic monitored DAS28. RA activity in both the groups is measured every 4 weeks to advise treatment escalation until remission is achieved. The patients are monitored every 4 weeks for the first 6 months and thereafter every 3 months for the next 6 months. The patients can access the web-based RAPID3 using the internet, which is supported by automated email reminders. The patients are educated on online completion of RAPID3 by the rheumatology team. Patients are asked to complete

online RAPID3 questionnaire every month. The patients also undertake pre-requested monthly CRP and other blood tests, the results of which are monitored by the rheumatology team. The team check the online RAPID3 score, blood results, discuss therapy changes with patients on the phone and forward an updated prescription to the hospital pharmacy for patients to collect at their convenience.

What are the possible benefits and risks of participating?
Use of telemonitoring of their self-assessed measure of RA activity will benefit patients by empowerment, convenience, and saving the time and costs of a face-to-face appointment. Implementation of treat-to-target strategy by telemonitoring will allow improvement in RA outcomes and reducing the adverse impact of RA on patients and wider society and economy. The patients are more likely to experience disease remission, reduction in disability, reduced working days lost, and decrease in requirements for future joint replacement surgeries. At the socio-economic level, there will be reduction in the need for carers, income benefits and overall long-term health costs.

Where is the study run from?
Royal National Orthopaedic Centre (UK)

When is the study starting and how long is it expected to run for?
January 2019 to June 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Gayatri Mittal
gayatri.mittal@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Gayatri Mittal

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1/1

Study information

Scientific Title
Telemonitoring of patient administered index RAPID3 to deliver NICE compliant treat-to-target strategy in early rheumatoid arthritis

Acronym
TelemonitorRA

Study objectives
Telemonitored RAPID3 is a suitable surrogate for DAS28-CRP to implement T2T strategy in early active RA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, London Westminster (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; Email: nrescommittee.london-westminster@nhs.net), ref: 19/LO /0673

Study design
Single-centre randomised parallel group interventional study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, to request a participant information sheet please contact Dr Gayatri Mittal on phone 0208385 3040 or email gayatri.mittal@nhs.net

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions
The patients will be randomised in blocks of four to the study or control group to monitor disease activity remotely by using patient administered index RAPID3 or in clinic using clinician administered DAS28 CRP. The randomisation will be done using opaque envelopes. After informed consent, patients will undergo screening for the study and baseline assessment will be carried out at the same time. Thereafter, the patients will be assessed every 4 weeks for the first 6 months and every 3 months for the next 6 months either by telemonitoring of RAPID3 or face-to-face DAS assessment in clinic. Patients will be educated on online completion of RAPID3 by rheumatology team. Patients will be asked to complete online RAPID3 questionnaire every month. The patients will also undertake pre-requested monthly CRP and other blood tests, which will be monitored by rheumatology team. The team will check the online RAPID3 score, blood results, discuss therapy changes with the patients on phone and forward an updated prescription to hospital pharmacy for patients to collect at their convenience. The patients in the telemonitoring group will also be assessed in clinic at 3, 6 and 12 months of the treatment. The patients will complete HAQ, ED-5D and WPAI questionnaires and undertake x-ray of hands and feet at the baseline and at 12 months. In addition, patients will have opportunity to be seen in clinic as ad-hoc in case of patient or clinician concern.

Intervention Type
Other

Primary outcome measure
Number of patients fulfilling the definition of remission defined as DAS28 <2.6 or low disease activity (DAS28 2,6-3.2) at 12 months of the RA treatment

Secondary outcome measures
1. Time required to achieve remission or low disease activity , measured by DAS28 CRP assessment at 3, 6 and 12 months of the treatment
2. Patient experience of remote monitoring of RA, measured at 12 months of the treatment by using a questionnaire asking for their rating on 0-10 scale of ease of use, simplicity of use, of benefit to them, caused difficulty, satisfaction level with the telemonitoring
3. Feasibility of the study assessed at 6 and 12 months by determining the number of people who have continued to participate in the study with drop out no more than 20% and that the rheumatology team is able to conduct the study without onerous effects on their other commitments
4. Cost effectiveness of telemonitoring of RA to deliver NICE compliant treatment. The cost of individual patient treatment will be calculated at 12 months of the treatment using the trust financial data

Overall study start date
15/01/2019

Completion date
30/06/2021

Eligibility

Key inclusion criteria

1. Aged 18 or above
2. Newly diagnosed RA fulfilling ACR/EULAR 2010 criteria for the diagnosis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Age < 18 years
2. Unable or unwilling to give informed consent
3. Women pregnant, breast feeding or at risk of conceiving
4. Prior treatment with DMARDs
5. Contraindications to DMARD therapy such as recurrent infections, pancytopenia, LFT derangement
6. Mental incapacity to participate in research study, complete RAPID3 and other patient-based study assessments
7. Inability of patient to complete web-based RAPID3 due to the lack of internet facilities or knowledge required to use internet
8. Currently participating or recently participated in another interventional trial

Date of first enrolment
01/07/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal National Orthopaedic Centre
Brockley Hill
Stanmore

United Kingdom
HA7 4LP

Sponsor information

Organisation
Royal National Orthopaedic Hospital

Sponsor details
Brockley Hill
Stanmore
England
United Kingdom
HA7 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/043j9bc42

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The study participants will be informed of the results. The results will be presented in local, regional, national and international meetings and published in peer-reviewed journals.

Intention to publish date
01/10/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Iva Hauptmmannova, Head of R&D, Research and Innovation Centre, Royal National Orthopaedic Centre, Stanmore, HA7 4LP. The identifiable data will be anonymised

before sharing. All the data will be transferred using secure email. The participant information sheet includes the possibility of data sharing with appropriate regulatory bodies and informed written consent would be taken before the actual recruitment of the patient into the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1	15/01/2019	12/02/2019	No	No
HRA research summary			28/06/2023	No	No