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Remote monitoring for rheumatoid arthritis flare during drug tapering

Submission date
24/11/2024

Recruitment status
Recruiting

Registration date
17/12/2024

Overall study status
Ongoing

Last Edited
17/12/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] 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) is a common disease affecting 1 in 100 adults in the UK. It causes joint pain, stiffness, and fatigue. Modern arthritis drugs can “switch off” the disease (known as remission) in around two-thirds of patients. However, these powerful drugs carry risks of serious side effects such as infection, need regular blood test monitoring, and are expensive. Recent research (including our own) has shown that up to half of patients with RA in remission can successfully reduce (taper) their arthritis drugs, meaning reduced medications, blood tests and side effects for patients and reduced costs for healthcare providers. It is important to monitor patients closely during drug tapering so that if an arthritis flare occurs this can be treated quickly. Currently, the only way of doing this is to examine their joints regularly during extra hospital visits, which are time-consuming and use up valuable hospital resources. This study aims to understand whether it is possible to detect arthritis flares remotely by measuring changes in physical activity. Patients with RA who are tapering their drugs within our local NHS RheumatOid Arthritis DMard tAPering (ROADMAP) clinic at Newcastle Hospitals will be invited to take part in this study. Participants will wear a wristwatch-like device (Axivity AX6) to record their physical activity and complete a short two-minute weekly questionnaire about their arthritis symptoms. Participants can choose to take part for three months or six months – the measurements recorded will not be used to guide their clinical care. The study objective is to look back and see if any changes in physical activity happened before the onset of arthritis flares. If successful, this study will take the first steps towards developing a new future technique for detecting arthritis flares without extra hospital visits.

Who can participate?
Patients aged 18 years old and over with a clinical diagnosis of RA made by a consultant rheumatologist

What does the study involve?
In this observational study, patients tapering DMARD therapy will wear a wrist accelerometer for up to 6 months. Retrospective analysis of the data will create a model to predict daily arthritis flare-up risk.

What are the possible benefits and risks of participating?
There are no direct benefits or significant risks to participants in this study

Where is the study run from?
Newcastle upon Tyne Hospitals NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
November 2024 to May 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR), UK

Who is the main contact?
Dr Kenneth Baker, kenneth.baker@ncl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
330151

Protocol serial number
NUTH 10866; NIHR303620

Study information

Scientific Title
Beyond Remission - work package 2

Study objectives

An observational study to demonstrate the feasibility and accuracy of accelerometry monitoring for the detection of rheumatoid arthritis flare during disease-modifying anti-rheumatic drug tapering

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending submission

Study design
Observational single-centre longitudinal cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Remote detection of arthritis flare in patients with rheumatoid arthritis who are tapering their arthritis drug treatment

Interventions
Observational study: Patients tapering disease-modifying anti-rheumatic drug (DMARD) therapy as part of routine standard care will be invited to wear a wrist accelerometer device for up to 6 months. Retrospective analysis of accelerometry data will be performed to create a prototype Bayesian statistical model to predict the daily risk of arthritis flare-ups recursively.

Intervention Type
Other

Primary outcome(s)
Rheumatoid arthritis flare, defined as a disease activity score in 28 joints with C-reactive protein (DAS28-CRP) ≥ 2.4, measured using data collected by the wrist accelerometer device at one time point

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/05/2028

Eligibility

Key inclusion criteria
1. Clinical diagnosis of RA made by a consultant rheumatologist
2. Disease activity score in 28 joints with C-reactive protein (DAS28-CRP) <2.4 at the point of enrolment to the study
3. Currently (or expected within the next 28 days) tapering of a DMARD (conventional synthetic,

targeted synthetic, or biologic)
4. Able to walk at least four metres independently without walking aids
5. Participants willing to commit to complete remote RA-FQ questionnaires and continuously wear monitoring devices

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Current or recent (within the past 12 months) use of rituximab
2. Current or recent (within the past 12 months) use of oral, intramuscular, intravenous or intra-articular glucocorticoids for arthritis treatment (note that topical glucocorticoids and short courses of systemic glucocorticoids for other indications such as lung or skin conditions are permitted)
3. Escalation of DMARD therapy (i.e. initiation of new DMARD or increase in DMARD dose) within the past 12 months (note that dose reductions are permitted)
4. Unable to read or communicate in English
5. Inability to provide informed consent
6. Age less than 18 years
7. Current diagnosis of a movement disorder
8. Physical disability that would prevent wearing a wrist device (e.g. bilateral upper limb amputation or congenital deformity)
9. Current pregnancy

Date of first enrolment
01/03/2025

Date of final enrolment
30/11/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication