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Understanding drug-free remission in rheumatoid arthritis

Submission date
16/11/2024

Recruitment status
Recruiting

Registration date
28/01/2025

Overall study status
Ongoing

Last Edited
12/02/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Background and study aims
Rheumatoid arthritis is a common disease affecting 1 in 100 adults in the UK. It occurs when the immune system mistakenly attacks the joints, causing pain, stiffness, fatigue, and potentially leading to joint damage and disability. Modern arthritis drugs help over a third of patients achieve remission, but these drugs can have side effects and require regular blood tests. This study aims to understand how some patients can stop taking arthritis drugs without their symptoms returning, known as "drug-free remission," and how this affects their feelings and future health.

Who can participate?
Patients who have previously stopped taking arthritis drugs in earlier studies will be invited to participate.

What does the study involve?
Participants will be asked to donate a small blood sample. Researchers will study the white blood cells and their protein markers to understand immune system changes in drug-free remission. Participants will also answer questions about their feelings and experiences, such as whether they feel cured and how stopping the drugs affects their hopes and concerns for their future health.

What are the possible benefits and risks of participating?
The study may help identify new ways to treat and prevent arthritis flare-ups and provide valuable information to support patients before and after drug withdrawal. However, as with any study, there may be risks associated with blood sample collection and sharing personal health information.

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 January 2026.

Who is funding the study?
Foundation for Research in Rheumatology (UK)

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

Study website
https://www.foreum.org/projects.cfm?projectid=228

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334887

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
10275, CPMS 66836

Study information

Scientific Title
SustaINed drug-Free remissiON in rheumatoId Arthritis

Acronym
SINFONIA

Study objectives
1. To characterise the immune phenotype and function of patients with rheumatoid arthritis in sustained drug-free remission
2. To identify, characterise and understand patients' experience of sustained drug-free remission over time

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Study design
Single visit observational study with optional qualitative interview

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other, Quality of life

Participant information sheet
To follow

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Immunological phenotyping and qualitative interview

Intervention Type
Other

Primary outcome measure
At a single time point:
1. Characterisation of CD4+ regulatory T cell and B cell phenotype in patients in sustained drug-free remission using conventional and spectral flow cytometry
2. Quantification of CD4+ regulatory T cell function in sustained drug-free remission through the use of in vitro autologous T cell suppression assays

Secondary outcome measures

To identify, characterise and understand patients' experience of sustained drug-free remission by interview at a single time point

Overall study start date
16/11/2024

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. Diagnosis of rheumatoid arthritis according to the 1987 American College of Rheumatology (ACR) (Appendix B) or 2010 ACR/European Alliance of Associations for Rheumatology (EULAR) classification criteria (Appendix C) applied at any time since diagnosis.
2. Previous or current use of a disease-modifying anti-rheumatic drug (conventional synthetic, targeted synthetic, or biological)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Unable to read or communicate in English
2. Inability to provide informed consent
3. Age less than 18 years
4. Current pregnancy

Date of first enrolment
01/03/2025

Date of final enrolment
19/12/2025

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor details
Newcastle Joint Research Office, 1st Floor Regent point, Regent Farm Road
Newcastle upon Tyne
England
United Kingdom
NE3 3HD
+44 1912336161
nuth.nuthsponsorship@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://newcastlejro.com/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Foundation for Research in Rheumatology

Alternative Name(s)
FOREUM

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
We aim to publish results from this study in medical journals and present them at medical and scientific conferences, as well as local and national patient organisations.

Intention to publish date
01/12/2026

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