Understanding drug-free remission in rheumatoid arthritis

Submission date	Recruitment status	[X] Prospectively registered
16/11/2024	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/01/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
12/02/2025	Musculoskeletal Diseases	[X] Record updated in last yea

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

Contact name

Dr Kenneth Baker

ORCID ID

http://orcid.org/0000-0002-6735-2911

Contact details

Translational and Clinical Research Institute, Room M4.089, Leech Building, Medical School, Newcastle University Newcastle upon Tyne United Kingdom NE2 4HH +44 191 208 2754 kenneth.baker@ncl.ac.uk

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

SustalNed drug-Free remissiON in rheumatold 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 drugfree 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

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