

Understanding drug-free remission in rheumatoid arthritis

Submission date 16/11/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/01/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/02/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Kenneth Baker

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

334887

Protocol serial number

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)

notYetSubmitted

Study design

Single visit observational study with optional qualitative interview

Primary study design

Observational

Study type(s)

Other, Quality of life

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

Immunological phenotyping and qualitative interview

Intervention Type

Other

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

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

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes