

# Understanding drug-free remission in rheumatoid arthritis

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

### ORCID ID

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

334887

### ClinicalTrials.gov (NCT)

Nil known

### 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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes