

# REmoval of Treatment for patients in REmission in psoriatic ArThritis - a Feasibility study [RETREAT(F)]

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| <b>Submission date</b><br>13/08/2012   | <b>Recruitment status</b><br>No longer recruiting                | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>07/11/2012 | <b>Overall study status</b><br>Completed                         | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>29/01/2018       | <b>Condition category</b><br>Skin and Connective Tissue Diseases | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Psoriatic arthritis is a type of arthritis that develops in some people who have the skin condition psoriasis. Affected joints become inflamed (swollen), stiff and painful. Drug treatments have been found to be effective but are expensive and may have serious side effects. Patients often ask to have drug treatments withdrawn or scaled down once their disease is stable. The aim of this study is to compare the effects of withdrawing versus continuing treatment in psoriatic arthritis patients.

### Who can participate?

Patients with psoriatic arthritis presenting to rheumatology outpatient departments in Leeds, Bradford and York, who are in a stable low disease activity state.

### What does the study involve?

Participants are randomly allocated to either withdraw treatment over 3 months or to continue treatment. Participants are reviewed in the clinic every 4 weeks to manage their treatment changes and monitor their response.

### What are the possible benefits and risks of participating?

Participants in the withdrawal group will benefit from a controlled reduction in their current medication with the possibility of being drug-free at the end of the study. If their disease gets worse, the last removed medication will be re-introduced in a step-wise manner, with use of steroids if required. Participants in both groups will benefit from a 4-month intensive review of their disease.

### Where is the study run from?

University of Leeds (UK).

### When is the study starting and how long is it expected to run for?

September 2012 to August 2013.

Who is funding the study?  
Arthritis Research UK.

Who is the main contact?  
Robin Waxman  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Philip Helliwell

**Contact details**  
University of Leeds  
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## Additional identifiers

**Protocol serial number**  
V1 14/09/2011

## Study information

**Scientific Title**  
REmoval of Treatment for patients in REmission in psoriatic ArThritis - Feasibility study [RETREAT (F)]: a randomised controlled feasibility study to compare withdrawal of therapy versus continuing therapy in low disease states in psoriatic arthritis

**Acronym**  
RETREAT (F)

**Study objectives**  
This feasibility study is designed to inform the sample size calculation for a full randomised controlled trial of treatment withdrawal in patients with psoriatic arthritis by assessing patient willingness to enter the trial, exploring barriers to recruitment, and determining the outcome of treatment withdrawal at 3 months. Participants will be randomized to treatment withdrawal or a control arm at a ratio of 2:1.

On 15/05/2013 the overall trial end date was changed from 31/08/2013 to 31/10/2013.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Leeds Research Ethics Committee

**Study design**

Feasibility study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Psoriatic arthritis

**Interventions**

This feasibility study is designed to inform the sample size calculation for a full randomised controlled trial of treatment withdrawal in patients with psoriatic arthritis by assessing patient willingness to enter the trial, exploring barriers to recruitment, and determining the outcome of treatment withdrawal at 4 months. Patients presenting to rheumatology outpatient departments in Leeds, Bradford and York, who are in a stable low disease activity state, will be invited to participate in a short trial period of treatment withdrawal. Participants will be randomized to treatment withdrawal or a control arm at a ratio of 2:1.

Patients randomized to withdraw will undergo a phased withdrawal of medication where the last treatment added will be the first treatment withdrawn. Treatment will be withdrawn in a stepwise fashion phasing out and stopping over three months. Participants will be reviewed in clinic every 4 weeks to manage treatment changes and monitor withdrawal response using the Minimal Disease Activity criteria.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Primary outcome(s)**

For this feasibility study we wish to know the proportion of eligible patients who are willing to undergo treatment withdrawal and the proportion remaining in minimal disease at the end of the study period. Within the three month treatment withdrawal period, a minimal disease activity (MDA) score of 5 or more (achievement of the minimal disease activity criteria) will be used to confirm continuing low disease activity.

**Key secondary outcome(s)**

Although no attempt will be made to stratify recruitment, relapse rate by drug withdrawn will be recorded. It is anticipated that the majority of patients will be taking TNF inhibitors at enrollment, but up to one third may be taking methotrexate alone.

**Completion date**

31/10/2013

# Eligibility

## Key inclusion criteria

1. Patients must have a diagnosis of peripheral psoriatic arthritis of more than 12 months duration (according to CASPAR Criteria)
2. Patients must be in minimal disease activity (as defined by the validated MDA criteria) with physician indicated stability of disease for the six months preceding screening
3. Age > 18 years at time of commencing study, either male or female patients
4. Women of childbearing age must ensure adequate contraception for the duration of the study, including those who are randomised to the withdrawal arm, in case of need to re-treat if disease flare should occur
5. Men consenting to the trial should ensure adequate contraception for any sexual partner for the duration of the study
6. Patients must have adequate screening blood tests prior to randomisation including FBC, U&E and LFT
7. Patients must be able to adhere to the study timetable and protocol, and be able to sign an informed consent document
8. Patients must have been on a stable dose of TNF or DMARD for the six month period directly preceding screening

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Key exclusion criteria

1. Women who are pregnant, lactating or planning pregnancy within 6 months of last dose of protocol treatment
2. Use of any investigational medications or products within four weeks of randomisation
3. Change on DMARD or TNF dose in the six months prior to screening

## Date of first enrolment

01/12/2012

## Date of final enrolment

01/03/2013

# Locations

## Countries of recruitment

United Kingdom

England

**Study participating centre**

**University of Leeds**

Leeds

United Kingdom

LS7 4SA

## **Sponsor information**

**Organisation**

University of Leeds (UK)

**ROR**

<https://ror.org/024mrx33>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Arthritis Research UK

**Alternative Name(s)**

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 01/08/2015   |            | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |