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

Submission date
13/08/2012

Recruitment status
No longer recruiting

Registration date
07/11/2012

Overall study status
Completed

Last Edited
29/01/2018

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 Patients often ask to have drug treatments withdrawn or scaled down once their disease is stable.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
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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/024mrxd33

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?
Results article	results	01/08/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes