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A feasibility study to test how effective is it to treat patients with mild psoriatic arthritis using only local steroid injections without being put onto more powerful arthritis drugs

Submission date
15/04/2019

Recruitment status
No longer recruiting

Registration date
26/04/2019

Overall study status
Completed

Last Edited
06/10/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 02/03/2021:

Background and study aims
Psoriatic Arthritis (PsA) is an inflammatory arthritis estimated to occur in 15% of people with psoriasis, affecting around 150,000 people in the UK. Two-thirds of people with PsA suffer progressive joint damage with associated disability. Psoriatic arthritis causes inflammation in and around the joints. It usually affects people who already have psoriasis, a skin condition that causes a red, scaly rash. People with PsA have similar functional and quality of life impairment to rheumatoid arthritis. PsA is associated with a reduced life expectancy related to the risk of comorbidities, particularly metabolic syndrome. It is likely that some patients are overtreated with conventional 'step up' therapy leading to unnecessary side effects for the patient and costs to the healthcare system. This trial will investigate the feasibility and acceptability of the study design to establish whether persons with mild PsA can be managed without disease-modifying antirheumatic drugs (DMARDs).

Who can participate?
Participants with newly diagnosed PsA will be eligible if they fulfil the following criteria:
1. Oligoarthritis (<5 joints involved)

What does the study involve?
The study involves treating affected joints directly with glucocorticoid injections in mild disease. In this study some patients receive the usual drugs (standard care), and others are only given painkillers and steroid injections into swollen joints. This is instead of the standard treatment where at first one drug is used then two drugs together and finally newer stronger biologic drugs for patients who don't respond to the other drugs. Injections are given as needed at 12 weekly visits up to 48 weeks. If any joint needs more than two injections in six months, patients start on the standard arthritis drugs. Patients have routine blood tests, have their joints examined and complete questionnaires at each visit. An ultrasound scan is carried out at the

start of the study to see if some joints that appear normal and pain-free may actually have some inflammation.

What are the possible benefits and risks of participating?
The drugs and injections used are all in current use and have well-known safety profiles. Delaying drug therapy will delay the risk of side effects of those medications (which may include nausea/vomiting, soreness in or around the mouth, rashes, diarrhoea, hair loss [usually mild], tiredness and effects on the immune system particularly after prolonged use). The steroid injections can increase sugar levels in diabetic patients for a few days and they may increase pain in the joints for a few days. Rarely they can result in the death of a bit of bone around a joint but this tends to be at higher doses. Also rarely a joint infection may occur and need antibiotic treatment or a small operation.

Where is the study run from?
1. Cambridge University Hospitals NHS Foundation Trust
2. Royal United Hospitals Bath NHS Foundation Trust
3. Oxford University Hospitals NHS Foundation Trust

When is the study starting and how long is it expected to run for?
March 2017 to February 2021

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Dr Anne Francis, anne.francis@ndorms.ox.ac.uk

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Previous plain English summary:

Background and study aims
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Who can participate?
Participants with newly diagnosed PsA will be eligible if they fulfil the following criteria:
1. Oligoarthritis (<5 joints involved)
2. Low disease activity (measured by PASDAS <3.2)
3. Low impact of disease (PSAID <=4)

What does the study involve?
The study involves treating affected joints directly with glucocorticoid injections in mild disease.

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Who is funding the study?
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Who is the main contact?
Dr Marion Watson, marion.watson@ndorms.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Laura Coates

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Additional identifiers

Clinical Trials Information System (CTIS)
2018-001085-42

ClinicalTrials.gov (NCT)
NCT03797872

Protocol serial number
CPMS 38512

Study information

Scientific Title
Clinical effectiveness of symptomatic therapy compared to standard step-up care for the treatment of low impact psoriatic oligoarthritis: a 2 arm parallel group feasibility study.

Acronym
POISE

Study objectives
1. To determine the feasibility of conducting of a future definitive trial to establish whether a subgroup of participants with
mild PsA can be safely and effectively managed without DMARDs.
The study will assess:
1.1. The proportion of participants referred to the PsA clinic who meet the inclusion criteria (with this mild disease phenotype as defined by oligoarthritis, no poor prognostic factors and PSAID ≤4)
1.2. The proportion of participants willing to consent to the study indicating that they find the intervention acceptable
1.3. The proportion of participants not offered DMARD therapy during the 48 week trial period (DMARD therapy will be offered if participants have active disease despite 2 doses of glucocorticoids within a 6 month period)

2. To develop the design of a future definitive trial to establish whether a subgroup of patients with mild PsA can be safely
and effectively managed without DMARDs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/05/2018, South Central- Oxford B Research Ethics Committee (Whitefriars, Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT, UK; Tel: +44 (0)2071048058; Email: nrescommittee.southcentral-oxfordb@nhs.net), ref: 18/SC/0261

Study design
Interventional randomised parallel trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psoriatic oligoarthritis

Interventions
The trial is a randomised open-label feasibility trial with two arms:
1. Standard care
2. Symptomatic therapy

The trial forms part of a “Trials within Cohorts” or TWiCs design where participants in the cohort may be offered interventional studies subject to meeting the relevant inclusion/exclusion criteria. Consent is requested in the cohort study for data to be used without further approach.

This is a randomised open-label feasibility trial assessing the acceptability of conservative management in mild PsA and the feasibility of a future definitive trial within a cohort in a “Trials within Cohorts” or TWiCs design. A maximum of 60 participants will be recruited (30 to the cohort, arm 1 as controls and 30, arm 2 receiving the intervention). The number is an estimate, as at present it is not known how many participants with mild disease will be eligible and willing to participate. It is estimated that around 15% of participants referred with new PsA may be eligible.

Each participant will be followed for 48 weeks within this trial and will then revert to standard care within the cohort. Patients in this study will attend for study visits at baseline and weeks 12, 24, 36 and 48. Patients in the intervention arm will also be able to attend for joint injections as required in between these visits via a trial helpline. At all visits, patients will be assessed clinically for disease activity and will be asked to complete patient-reported outcomes. Adverse event information will be sought at each visit and recorded, assessed and reported as required by the protocol.

Data will be entered into an electronic CRF and appropriate validation checks carried out. Data will be analysed in accord with a statistical analysis plan starting with the null hypothesis that there is no difference in the proportion of participants achieving a PASDAS good response at week 24 between any of the two treatment arms. If this is significant at the 5% level further analyses will compare each intervention against the control arm.

Intervention Type
Drug

Phase
Not Applicable

Primary outcome(s)

The feasibility of conducting a future definitive trial to establish whether a subgroup of participants with mild PsA can be safely and effectively managed without DMARDs.
The study will assess:
1. The proportion of participants referred to the PsA clinic who meet the inclusion criteria (with this mild disease phenotype as defined by oligoarthritis, no poor prognostic factors and PSAID ≤4)
2. The proportion of participants willing to consent to the study indicating that they find the intervention acceptable
3. The proportion of participants not offered DMARD therapy during the 48 week trial period (DMARD therapy will be offered if participants have active disease despite 2 doses of glucocorticoids within a 6 month period)

Key secondary outcome(s))
To help plan a future definitive study, if this feasibility study is successful, the researchers will collect data on the response to treatment as measured using the Psoriatic Arthritis Disease Activity Score (PASDAS) which is calculated from clinical assessments (disease activity visual analogue scale, swollen and tender joint counts, Leeds enthesitis index) and patient-reported items on questionnaires (SF-36) at 0, 12, 24, 36 and 48 weeks.

Completion date
02/02/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 02/03/2021:

1. Participants consented to the PsA inception cohort (MONITOR-PsA) and to be approached for alternate interventional therapies
2. Participants with mild disease as defined by:
2.1 Oligoarticular disease with <5 active joints at baseline assessment
3. Participant is willing and able to give informed consent for participation in the trial
4. Male or female
5. Aged 18 years or above
6. Female participants of child bearing potential and male Participants whose partner is of child bearing potential must be willing to ensure that they or their partner use effective contraception during the trial and for 3 months thereafter if receiving DMARD therapy (excluding sulfasalazine)
7. Participant has clinically acceptable laboratory results within 6 weeks of enrolment:
7.1 Haemoglobin count >8.5 g/dL
7.2 White blood count (WBC) >3.5 x 10^9/L
7.3 Absolute neutrophil count (ANC) >1.5 x 10^9/L
7.4 Platelet count >100 x 10^9/L
7.5 ALT and alkaline phosphatase levels <3 x upper limit of normal
7.6 eGFR
7.7 In the Investigator’s opinion, is able and willing to comply with all trial requirements
7.8 Willing to allow his or her GP and consultant, if appropriate, to be notified of participation in the trial

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Previous inclusion criteria:

1. Participants consented to the PsA inception cohort (MONITOR-PsA) and to be approached for alternate interventional therapies.
2. Participants with mild disease as defined by:
2.1 Oligoarticular disease with < 5 active joints at baseline assessment.
2.2 Low disease activity as defined by a PsA disease activity score (PASDAS) < = 3.2.
2.3 Low impact of disease as defined a PsA impact of disease (PSAID) < = 4.
3. Participant is willing and able to give informed consent for participation in the trial.
4. Male or female.
5. Aged 18 years or above.
6. Female participants of child bearing potential and male Participants whose partner is of child bearing potential must be willing to ensure that they or their partner use effective contraception during the trial and for 3 months thereafter if receiving DMARD therapy (excluding sulfasalazine).
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7.5 ALT and alkaline phosphatase levels <3 x upper limit of normal
7.6 In the Investigator's opinion, is able and willing to comply with all trial requirements.
7.7 Willing to allow his or her GP and consultant, if appropriate, to be notified of participation in the trial.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1

Key exclusion criteria
1. >=1 poor prognostic factors for psoriatic arthritis, from:
1.1 Raised C reactive protein (CRP) defined as >4g/dl for standard non-hsCRP
1.2 Radiographic damage defined as the presence of >= 1 erosion on plain radiographs of the hands and feet
1.3 Health assessment questionnaire (HAQ) score >1
2. Contraindications to non-steroidal anti-inflammatory drugs

3. Previous treatment for articular disease with synthetic DMARDs (including methotrexate, leflunomide or sulfasalazine) or biologic DMARDs (including TNF, IL12/23 or IL17 inhibitor therapies) or targeted synthetic DMARDs (PDE4 of JAK inhibitor therapies).
4. Female patient who is pregnant, breast feeding or planning pregnancy during the course of the trial.
5. Significant renal or hepatic impairment.
6. Scheduled elective surgery or other procedures requiring general anaesthesia during the trial.
7. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the patients at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial.
8. Patients who have participated in another research trial involving an investigational product in the past 12 weeks.

Date of first enrolment
24/04/2019

Date of final enrolment
16/07/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way

Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: NIHR-CS-2016-16-016

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to limited data availability.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/01/2022	14/02/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 6.0	11/11/2025	11/11/2025	No	Yes
Protocol file		27/08/2019	06/10/2022	No	No