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The development of a Psoriasis Rapid Access Clinic (P-RAC)

Submission date
08/11/2018

Recruitment status
No longer recruiting

Registration date
11/12/2018

Overall study status
Completed

Last Edited
10/08/2022

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Background and study aims
The Psoriasis Rapid Access Clinic (P-RAC) is being developed to enable newly diagnosed patients with psoriasis (an inflammatory long-term skin condition) to receive early access to appropriate and personalised care. This will enable a well-rounded (or holistic) management of their psoriasis and encourage self-care.

Who can participate?
Patients who have newly diagnosed psoriasis, or those who have been diagnosed in the last 2 years, who are aged 16 or over, live in Salford (Greater Manchester, UK) and are registered with a GP in this area

What does the study involve?
Patients attend a specialist psoriasis clinic. At the clinic, patients have consultations with a dermatologist (a specialist skin doctor), a nurse and a health psychologist or health coach. They have a thorough assessment of their psoriasis, which involves examining their skin, and checking for other conditions which sometimes occur in people with psoriasis, such as psoriatic arthritis. Patients are involved in creating their own management plan, with an emphasis on getting the best understanding of psoriasis, skin treatments and focusing on treatment goals. Data are collected relating to the patient’s psoriasis during these consultations by examining them and asking questions. Patients also complete some questionnaires. These consist of general questions about them, their health, family history of disease, psoriasis and how this affects them. A nurse takes some measurements including blood pressure, weight, height and waist measurement. Patients are asked to attend the clinic again 4 weeks and 24 weeks later (about 6 months) so that assessments including questionnaires can be repeated, and to ensure the patients is receiving the right treatment for their psoriasis. Patients are also asked to donate blood samples at the first visit which is processed for key indicators of health e.g. cholesterol, creatinine, as well as sera (a blood component) and DNA (a person's genetic code). The latter two are stored for future research; this provide a new opportunity to learn more about psoriasis in this group of patients.

What are the possible benefits and risks of participating?
There are several benefits of taking part. People who have recently developed psoriasis will

have access to a specialist team much more quickly than is normal in the NHS at present. They will have an opportunity to learn about psoriasis, understand how it can affect various aspects of their health and wellbeing, make a plan to treat their psoriasis and stay healthy. One disadvantage may be the time taken to attend clinic and complete the questionnaires. Some questions about how patients feel may be personal and sensitive. The healthcare professionals at the clinic will provide a supportive environment for patients and signpost appropriate help and support that they may need. There may be some brief discomfort associated with having a blood test.

Where is the study run from?
1. The University of Manchester (UK)
2. Salford Royal NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2018 to August 2020 (updated 18/10/2019, previously: March 2020)

Who is funding the study?
Health Innovation Manchester (UK). The consultant dermatologist for this project also has an unrestricted research grant from Celgene (UK).

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number
242032

ClinicalTrials.gov number

Secondary identifying numbers
Protocol number: NHS001399, IRAS project ID: 242032

Study information

Scientific Title
The development of a Rapid Access Clinic for patients with Psoriasis (P-RAC)

Acronym
P-RAC

Study objectives
The aim of this study is to determine the feasibility of setting up a Rapid Access Clinic for patients who have recently been diagnosed with psoriasis. This will be achieved by setting up, delivering and assessing a pilot clinic in Salford.

Ethics approval required
Old ethics approval format

Ethics approval(s)

North West - Liverpool Central Research Ethics Committee, 02/10/2018, ref: 18/NW/0596

Study design
Interventional single-centre non-randomised feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
At baseline, patients will have a full assessment of their psoriasis by a specialist dermatologist, which will include a physical examination, definitive diagnosis, severity scoring, and screening for comorbidities which are known to be increased amongst patients with psoriasis including psoriatic arthritis. Additionally, a research nurse will perform height, weight and blood pressure measurements and collect a full medical history Optional blood samples will be taken for determination of cardiovascular disease risk factors and future research.

The nurse and a health psychologist will guide patients through questionnaires on lifestyle factors (such as smoking, exercise and alcohol consumption), a qualitative and quantitative assessment of a patient's feelings and thoughts about psoriasis and its treatments, as well as quality of life measures: The health psychologist will use motivational interviewing techniques in partnership with the patient to set goals for their disease management and create an holistic care plan.

Follow-up appointments will take place at 4 and 24 weeks. The dermatologist's assessment will be repeated, and at 4 weeks the results of the cardiovascular risk (QRISK3) will be reported to the patient's GP. The nurse will repeat height, weight and blood pressure measurements and record any changes in medication or medical history. The patient will repeat questionnaires and meet with the health psychologist to determine any changes in the care plan.

Intervention Type
Mixed

Primary outcome measure
Feasibility and practicality of a Psoriasis Rapid Access Clinic for newly diagnosed patients with psoriasis, assessed using:

1. Recruitment rate recorded as the number of eligible participants seen at the clinic, and the continuation rate of patients to follow-ups at 4 and 24 weeks
2. The cost-effectiveness of the clinic determined by the set up costs, running costs and the longer-term health economic gains e.g. improvement in work productivity (Work Productivity and Activity Impairment questionnaire at baseline and 24 weeks)
3. Does a patient's understanding of psoriasis improve with the P-RAC intervention? (Determined by Understanding of psoriasis and treatment questionnaires at all time points)
4. Does the intervention lead to improvements in a patient's physical and emotional well-being? (Determined by changes from baseline to week 4 and week 24 follow-up measurements in: weight and waist circumference, anxiety and depression (using the Hospital Anxiety and Depression Scale), Generic Health Utility Index (Patient Baseline EuroQol – EQ5D), Psoriasis extent and severity (measured by physical examination (using measures such as Simplified Psoriasis Index, Physician Global Assessment and Psoriasis Area and Severity Index) and patient answered Dermatology Life Quality Index), as well assessments of smoking, alcohol consumption and exercise.

Secondary outcome measures
1. The pathophysiology and treatment of early psoriatic disease amongst this patient cohort, assessed by collecting blood samples at baseline which will be processed and stored for future genomic and proteomic research to learn more about the cause of psoriasis and better inform treatment options in the future
2. The prevalence of comorbidities including psoriatic arthritis (using Psoriasis epidemiology Screening Tool and physical examination at baseline) , depression and anxiety (using the Hospital Anxiety and Depression Scale questionnaire as well as qualitative data at all time points), and cardiovascular disease risk factors (baseline only, using QRISK3).

Overall study start date
01/04/2018

Completion date
31/07/2020

Eligibility

Key inclusion criteria
1. Aged 16 years or older
2. Currently living in Salford
3. Registered with a Salford GP
4. Developed psoriasis over the past 2 years or prospective new diagnoses of psoriasis occurring in Salford during the course of this pilot study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

50

Total final enrolment
39

Key exclusion criteria
1. Psychiatric or other disorder that may impact on informed consent
2. Currently under the active care of hospital dermatology services for psoriasis
3. On systemic therapy or ultraviolet (UV) therapy for psoriasis

Date of first enrolment
26/11/2018

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal NHS Foundation Trust - The Willows Centre for Healthcare
Lord's Avenue
Salford
United Kingdom
M5 5JR

Sponsor information

Organisation
The University of Manchester

Sponsor details
Oxford Road
Manchester
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United Kingdom
M13 9PL

Sponsor type
University/education

Website
www.manchester.ac.uk

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research organisation

Funder Name
Health Innovation Manchester

Funder Name
Celgene - unrestricted research grant

Results and Publications

Publication and dissemination plan
The trialists plan to disseminate their findings via international conferences, peer-reviewed journals, with key stakeholders and policy makers and researchers. They will also feed the results back to the service centres involved.

Intention to publish date
31/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly accessible repository within The University of Manchester by the end of 2020. Anonymised data may be accessed and analysed by members of the project team and with researchers collaborating with members of the project team on the analysis of these data. Consent from participants was not sought for sharing raw data publicly. Therefore, external researchers seeking to access the data for use in future projects must do so via request to the Chief Investigator (or his delegate), and projects using the data must have been approved in accordance with contemporary UK ethical and regulatory processes pertaining to the release of anonymised data under these circumstances.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	Research letter	15/03/2022	10/08/2022	Yes	No
HRA research summary			28/06/2023	No	No