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Total burden of psoriasis

Submission date	Recruitment status	[X] Prospectively registered
27/06/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/07/2024	Skin and Connective Tissue Diseases	

Plain English summary of protocol

Background and study aims
Psoriasis is a common skin disorder affecting over 1 million people in England. There are many health complications which are associated with psoriasis. The purpose of the TUDOR study is to find out whether diagnosing psoriasis related health complications earlier (than normally in standard NHS care) leads to an improvement in physical health of the patient.

Who can participate?
Psoriasis patients between the ages of 18-70 who meet the study inclusion criteria can take part in the study.

What does the study involve?
People who participate in this study will need to complete questionnaires regarding their condition and attend clinical assessments which will include a physical examination.

What are the possible benefits and risks of participating?
By participating in the TUDOR study participants will be benefiting from a clinical assessment of their psoriasis by a qualified clinician, meaning that the severity of their condition and associated symptoms will be assessed by a qualified clinician. Participating in the study will also provide the research team with vital information about living with psoriasis and the measures that may need to be put in place to improve the care and support of psoriasis patients in the future. However taking time in the study requires time commitment to complete the study questionnaires and attend the clinical assessments. Some of the questions asked at the clinical assessments maybe of a personal or sensitive nature.

Where is the study run from?
The study will be carried out in 4 centres in the UK. Participants will be invited to take part in the study by their GPs via a postal invitation letter. GPs will identify potential participants from their practice database.

When is the study starting and how long is it expected to run for?
June 2015 to November 2021 (updated 03/08/2021, previously: May 2020)

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

Who is the main contact?
Ms Claire Davies – Senior Trial Manager

Contact information

Type(s)
Public

Contact name
Mrs Claire Davies

Contact details
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University of Leeds
Leeds
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31138

Study information

Scientific Title
TUDOR – Total Burden of Psoriasis

Acronym
TUDOR

Study objectives
The aim of the TUDOR study is to find out whether diagnosing psoriasis related health complications earlier (than normally in standard NHS care) leads to an improvement in physical health of the patient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West – Central Bristol Research Ethics Committee, 20/06/2016, ref: 16/SW/0161

Study design
Randomised; Interventional; Design type: Screening, Process of Care, Active Monitoring

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Specialty: Primary Care, Disease: Skin/ Papulosquamous disorders, Inflammatory/ Certain disorders involving the immune mechanism

Interventions
1. Clinical Assessment including a physical examination and completion of questionnaires related to psoriasis and quality of life (QoL)
2. Participants in the standard care arm of the trial will be requested to complete postal questionnaires regarding their condition and QoL at baseline and 12 months from trial registration date. Participants will then be invited to attend a clinical assessment at 24 months and also complete further questionnaires at the assessment visit
3. Participants in the trial arm will be invited to attend clinical assessments at baseline, 12 months and at 24 months. At each of the assessment visits participants will be requested to complete the same questionnaires as the standard care arm participants

Intervention Type
Other

Primary outcome measure
Physical function, measured by the Health Assessment Questionnaire and Disability Index (HAQ-DI) score at 24 months.

The primary outcome will be analysed using a fixed effects zero-inflated beta regression model adjusting for the stratification factors, HAQ-DI measured at baseline, other relevant baseline covariates, and treatment arm.

Secondary outcome measures
1. Disease activity for people diagnosed with psoriatic complications at 24 months post registration. Disease specific questionnaires will be analysed using multivariable fixed effects models, adjusting for the stratification factors and relevant baseline covariates. This will be based on data collected at 24 months post registration.
2. The diagnostic accuracy of an updated symptom questionnaire for identification of psoriatic disease. The diagnostic accuracy of the questionnaire will be assessed by estimating of the

sensitivity and specificity, positive and negative predictive values, and AUCs of the questionnaires, against the gold standard for diagnosing psoriatic disease. Regression-based sensitivity analysis, incorporating the possibility of dependence in the outcomes will be utilised to explore the additional explanatory power of the updated questionnaire. This will be measured either at baseline or 24 months depending upon the arm of the study.
3. To compare the sensitivity and specificity of the updated symptom screening tool with the symptom questionnaire currently approved for use in standard care. The differences between the updated and the currently approved questionnaires in terms of their sensitivity and specificity, positive and negative predictive values, and AUCs will be assessed. Where participants have completed both questionnaires, adjusted McNemar's tests, which account for clustered data, will be used to compare sensitivity and specificity. To examine the optimal method for screening for psoriatic disease, diagnostic questionnaires and their different cut points will be compared using receiver operator characteristic (ROC) curve analysis. This will be measured either at baseline or 24 months depending upon the arm of the study.
4. The impact of psoriatic complications on health-related quality of life and work productivity. Quality of Life and Work Productivity questionnaires will be analysed using a mixed effects model, adjusting
for the stratification factors, other relevant baseline covariates and treatment arm. The model will also adjust for fixed effects as well as random effects where relevant.
5. To identify risk factors associated with a longer duration to diagnosis of psoriasis related health complications. Mixed effects generalised additive models will be used to assess the association between age, sex and psoriasis severity on time to diagnosis in patients diagnosed with psoriasis related health complications, allowing for the possibility of non-linear effects between explanatory variables and response.
6. The association between severity of psoriasis and the development of psoriasis related health complications. The development of psoriasis related health complications will be analysed using a fixed effects zero-inflated beta regression model adjusting for the stratification factors, SAPASI (psoriasis severity measure), HAQ-DI measured at baseline, other relevant baseline covariates and treatment arm, at 24 months post registration.
7. To explore the extent to which certain candidate risk factors are associated with the development of psoriatic disease in people with psoriasis. Mixed effects generalised (logistic) effects models will be used to assess the extent to which age, sex, psoriasis severity, psoriatic disease duration and other risk factors are associated with the development of psoriatic complications in people with psoriasis.
8. The prevalence of inflammatory back pain in people with psoriasis. The prevalence of inflammatory back pain in the trial population will be calculated, together with 95% confidence intervals at baseline and at 12 and 24 months, depending on the arm of the study. The incidence of inflammatory back pain in the ES arms will be calculated, together with 95% confidence intervals at the 12 and 24 month assessments.

Overall study start date
01/06/2015

Completion date
30/11/2021

Eligibility

Key inclusion criteria
At all participating GP practices, patients will be eligible to take part in the trial if they meet the following criteria:

1. Males and females age 18-70 at time of recruitment
2. Their primary care record contains a Read Code for psoriasis at any time prior to their date of recruitment
3. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
Between 1916 and 2384 participants (depending on the number of GP practices opened to recruitment, number of participants recruited per GP practice and the drop-out rate of participants and GP practices) UK Sample Size: 1916-2384

Total final enrolment
2225

Key exclusion criteria
Participant Exclusion Criteria:
1. A prior diagnosis of psoriatic complications relevant to the study
2. Inability to comply with the study follow-up schedule
3. Unsuitable to participate in the study as determined by the screening GP
4. Previously participated in the TUDOR trial (in the case of participants who may move between participating GP practices due to house move or other reasons)

Date of first enrolment
07/11/2016

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
St Luke's Hospitals
Little Horton Lane
Bradford
United Kingdom
BD5 0NA

Study participating centre
Haywood Hospital, Staffordshire and Stoke-on-Trent Partnership NHS Trust
Morston House
The Midway
Newcastle-under-Lyme
Staffordshire
United Kingdom
ST5 1QG

Study participating centre
Chapel Allerton Hospital
Chapeltown Road
Leeds
United Kingdom
LS7 4SA

Sponsor information

Organisation
Royal United Hospitals Bath NHS Foundation Trust

Sponsor details
Combe Park
Bath
Avon
Somerset
England

United Kingdom
BA1 3NG

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/058x7dy48

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/05/2021

Individual participant data (IPD) sharing plan
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security), and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing, and believe it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

IPD sharing plan summary

Available on request, Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		22/07/2024	23/07/2024	Yes	No