British Society for Rheumatology Psoriatic Arthritis Register (BSR-PsA)

First published: 01/06/2020

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS35567

Study ID

35568

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

The British Society for Rheumatology Psoriatic Arthritis Register (BSR-PsA) is a multi-centre prospective cohort study of persons who meet the CASPAR classification criteria for psoriatic arthritis and:(a) Are starting a biologic

disease-modifying anti-rheumatic drug (bDMARD) or targeted synthetic DMARD (tsDMARD) that is approved or recommended for the treatment of PsA in the United Kingdom, having never previously received that particular agent, or(b) Have never received a boDMARD, bsDMARD, or tsDMARD agent.These groups comprise the exposed cohort and comparison cohort, respectively, and bDMARDs may include originator or biosimilar products. Standardised questionnaires are completed by the participants, and clinical data is obtained from the rheumatologist and / or the patients' medical notes.The study evaluates the long-term course of PsA and, patients are followed up annually, comprising patient and treatment characteristics, clinical parameters, patient-defined benefit, quality of life and serious adverse events. In addition, patients starting a bDMARD or tsDMARD (either at recruitment or subsequently) will be followed up three and six months after the commencement of that therapy, with the follow-up schedule being 'reset' in the event of switching between therapies. Questionnaire follow-up is tied to patients' anticipated clinical visit schedule, and clinical centres are contacted regarding any patients lost-to-follow- up. Safety issues, serious adverse events and supplementary information are collected by standardised forms. Once recruited, participants remain eligible for follow-up irrespective of any changes to their therapy.

Study status

Ongoing

Research institutions and networks

Institutions

University of Aberdeen

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jones Gareth

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 05/10/2017

Study start date
Actual: 20/09/2018

Data analysis start date
Planned: 01/08/2020

Date of final study report
Planned: 31/01/2023

Sources of funding

- Non-for-profit organisation (e.g. charity)

More details on funding

British Society for Rheumatology

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Website: www.abdn.ac.uk/bsr-psaProtocol registration: www.researchregistry.com (ID: researchregistry3801)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

The overall aim is to:• The impact of PsA on the individual, including function, work, quality of life and economic impact,• The natural history of PsA, including clinical and social (e.g. work) outcomes in the medium- to long-term and the impact of disease phenotype on disease outcome,• The use of bDMARDs/tsDMARDs, including effectiveness and predictors of treatment response,

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Psoriatic arthropathy

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

1446

Study design details

Outcomes

As described above, the BSR-PsA is set up to answer a number of questions related to natural history, outcome, treatment effectiveness and co-morbidities. Different analyses will have different end points, including:• Minimum disease activity,• Incidence of serious infection,• Adverse work outcome, and• Quality of life.

Data analysis plan

Initial analyses will consist of comparisons in between cohorts. The precise analysis will depend on the specific question being addressed, but all analyses will have a detailed pre-specified analysis plan. As an indicative example of the sort of analysis to be conducted.Differences in treatment outcome (Minimal Disease Activity) between exposed / non-exposed groups would be examined with simple descriptive statistics. A logistic model would then be fitted to estimate the odds ratio for MDA between patients. The model would be statistically adjusted for other exposures and patient characteristics associated with both the primary exposure and the outcome, to control for potential

confounding.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No