

Frequency and duration of clinical remission in patients with peripheral psoriatic arthritis requiring second-line drugs. A 6-year, case-control study.

Submission date 25/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/10/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Prato/33

Study information

Scientific Title

Acronym

PSARE (PSoriatic Arthritis REmission)

Study objectives

Studies on the efficacy of traditional Disease-Modifying Anti-Rheumatic Drugs (DMARDs) in the treatment of Psoriatic Arthritis (PsA) show a significant efficacy compared to placebo, with a response ratio ranging from 20% to 50% of the patients. Better results have been obtained with leflunomide and anti-tumor necrosis factor drugs (anti-TNF α), with a response rate of 50%-70%. Similarly to rheumatoid arthritis (RA), response to therapy in PsA is usually measured in terms of percentage improvement with respect to baseline, but rarely patients have been evaluated for clinical remission. Moreover, differently from RA, remission criteria for PsA have not yet been defined. However, in keeping with other authors, over 15 years of activity of our rheumatologic centre, we noted PsA patients who experienced prolonged remission both during treatment and after therapy interruption. We designed a prospective, follow-up, case-control study to evaluate the frequency of clinical remission in patients with peripheral PsA, and the duration of remission episodes both during treatment and over the off-therapy follow-up period.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Traditional DMARDs and all treatments employed in the study had the Italian Ministry of Health approval for PsA patients when the trial started in 2000. The trial obtained an automated approval from the Ethical Committee of the Hospital of Prato.

Study design

Case-control study

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Peripheral psoriatic arthritis

Interventions

Traditional DMARDs vs anti-TNF agents

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Modified American College of Rheumatology (ACR) criteria for clinical remission

Key secondary outcome(s)

Duration of clinical remission during treatment and after therapy interruption, to evaluate the ACR 20, 50, 70 response rates at the end of follow up, and to evaluate the correlation between initial clinical and laboratory variables and the frequency of remissions.

Completion date

31/12/2005

Eligibility

Key inclusion criteria

Case patients: consecutive new outpatients with peripheral psoriatic arthritis requiring second-line drugs

Controls: consecutive new outpatients with rheumatoid arthritis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Patients with inflammatory spinal pain at presentation or during the disease course, or meeting the modified New York criteria for ankylosing spondylitis, and those with contraindications to the use of traditional DMARDs and anti-TNF α drugs.

Date of first enrolment

01/01/2000

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Italy

Study participating centre

Hospital of Prato

Prato

Italy
59100

Sponsor information

Organisation

Hospital of Prato (Italy)

ROR

<https://ror.org/03gbp6p96>

Funder(s)

Funder type

Other

Funder Name

Investigator-funded (Italy)

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	01/06/2008		Yes	No