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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

Registration date
26/02/2007

Last Edited
02/10/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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-TNFα), 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

Secondary study design
Case-control study

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
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.

Overall study start date
01/01/2000

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
400

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-TNFα 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)

Sponsor details
(c/o Dr Fabrizio Cantini)
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03gbp6p96

Funder(s)

Funder type
Other

Funder Name
Investigator-funded (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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