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NON TOPICAL PHARMACOLOGICAL TREATMENT OF EARLY, UNTREATED (DMARD-NAÏVE, SYSTEMIC THERAPY-NAÏVE) PSORIATIC DISEASE: A SYSTEMATIC REVIEW

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Background: Psoriatic disease (PsD) refers to a systemic condition, probably driven by chronic and complex inflammatory mechanisms. PsD patients experience a fickle mixture of cutaneous (nail dystrophy, psoriatic lesions spectrum) and musculoskeletal (MSK: arthritis, enthesitis, dactylitis, spondylitis) inflammatory features, variously associated with other co-morbidities (ocular or bowel inflammatory disease, increased cardiovascular risk and metabolic syndrome).

Current evidence is limited in respect of the management of early, treatment-naïve PsD.

Objectives: To assess the literature with a focus on pharmacological interventions in early, treatment-naïve PsD.

Methods: Seven research questions were formulated according to the PICO approach: are interventions effective in obtaining control of overall PsD activity? Are interventions effective on peripheral arthritis? On dactylitis? On spondylitis? On enthesitis? On skin and nails?

The search was designed as a systematic review of the literature. Early PsD was defined as disease duration ≤2 years, except for studies investigating outcomes restricted to the skin.

Criteria for including records were: adult human participants; participants with cutaneous features of PsD; participants with MSK features of PsD; double blind, single blind and non-blinded RCT; well-designed prospective studies/series.

The search protocol was registered on PROSPERO [1], the search was performed between June 2018 and January 2019.

Results: Resources available were widely explored (4 databases, 5 trial registers, 5 conference archives; see figure). The search retrieved 156,348 references (publication range 1946–2019) of which 308 (0.2%) qualified for full-text-assessment (FTA, figure); 7 (0.0004%) fulfilled the selection criteria and only 4 underwent data extraction.

Ref. type	PsD feature targeted	Intervention (success)	Primary outcome
1 RCT	Skin	Secukinumab (yes) vs fumarates (no)	PASI75
2 cohort	MSK	MTX part of T2T (yes)	Unclear
3 RCT	MSK	MTX (partial)	Joint count
4 RCT	Skin	Apremilast (yes)	PGAxBSA

Meta-analysis was impossible due to data heterogeneity (disease classification criteria, outcome measures and intervention durations). Although no clinical study adopted comprehensive composite indexes as primary outcome measures, 40% of FTA references described more than one component of PsD (i.e.: cutaneous and MSK) at least within the baseline characteristics. A substantial proportion of FTA references did describe, among participants recruited, many who were early untreated PsD at baseline. Unfortunately, separate analyses were not possible due to unavailability of the original datasets. A subset (10%) of the FTA references did not report on the participants' exposure to previous treatment.

Conclusion: Few studies addressed early, treatment naïve PsD. The underrepresentation of such data may be related to trial-enrolment criteria. More studies are needed to investigate this identified unmet need.

REFERENCES:

- [1] http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018097366

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FLOW DIAGRAM

Figure

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IXEKIZUMAB IMPROVES THE SIGNS AND SYMPTOMS OF PSORIATIC ARTHRITIS REGARDLESS OF SEX, DURATION OF DISEASE, OR BODY MASS INDEX IN TWO RANDOMIZED, PHASE 3 CLINICAL TRIALS

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Background: Ixekizumab (IXE) is a high-affinity monoclonal antibody that selectively targets interleukin-17A. During 24 weeks (wks) of treatment, IXE resulted in significantly greater improvements versus placebo (PBO) in the signs and symptoms of active psoriatic arthritis (PsA) in two randomized Phase 3 studies.^{1,2}

Objectives: To evaluate the consistency of clinical response with IXE in demographic subsets of patients (pts) with active PsA.

Methods: Clinical response to IXE was analyzed from an integrated database of 2 randomized, double-blind, Phase 3 studies in biologic Disease