Title of Research
Construct Validity and Responsiveness of Instruments Used in Psoriatic Arthritis Clinical Trials

Lead Researcher
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Summary of Research
Psoriatic arthritis (PsA) is a chronic inflammatory arthritis affecting up to one-third of patients with psoriasis. Psoriatic arthritis is a clinically heterogeneous disorder with distinct manifestations including peripheral arthritis, spondylitis, enthesitis, and dactylitis, in addition to skin and nail features. Nearly one-half of patients will have erosions, approximately one quarter within the first six months of disease onset. Furthermore, patients with PsA have lower health related quality of life (HR-QoL) independent of skin psoriasis. The heterogeneity of clinical manifestations in PsA complicates assessment of PsA outcomes. Over the past two decades, our knowledge about PsA and available therapies to treat PsA has evolved. However, the tools available to measure therapeutic responses have not adapted quite as rapidly. PsA outcome measures are largely adopted from rheumatoid arthritis (RA). Similar to RA, randomized controlled trials (RCTs) of PsA focus on peripheral arthritis as the primary outcome. Other PsA-specific manifestations (for example spondylitis, dactylitis, enthesitis, skin disease) are often assessed as secondary outcomes. We have recently updated the PsA core domain set, the key domains to be measured in PsA RCTs and longitudinal observational studies (LOS). This updated core domain set was developed with patient input. The Outcome Measures in Rheumatology (OMERACT)-Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) working group now intends to update the core measurement set, the key instruments to be measured in clinical trials to reflect the many ways in which patients experience psoriatic arthritis. In doing so, we seek to identify a parsimonious set of instruments that are feasible, reliable and valid to measure the core domains. The objective of this study is to examine the psychometric properties of existing outcome measures used in RCTs of PsA. Our hypothesis is that some measures are better than others in measuring disease activity in terms of responsiveness and discrimination.

Study Design
The aim of this study is to better understand how the outcome measures used to measure disease activity and impact in psoriatic arthritis work in clinical trials. The study will be based on the analysis of existing trial data.

The first aim is to examine construct validity of outcome measures used in PsA RCTs by determining the convergent and divergent intra- and inter-domain correlation. This aim will address the correlation among change on individual instruments with change in instruments within the same domain (e.g. among measures of peripheral arthritis activity) and between domains (e.g. peripheral arthritis activity and patient global response).

The second aim is to examine the responsiveness of outcome measures used in PsA RCTs. In this aim, we will examine ceiling and floor effects of available outcome measures and the range of effect sizes for each outcome measure.

We will report the mean and range of the correlations for each group (before treatment and after treatment). Separating the responsiveness of outcome measures from therapy effectiveness is difficult. Our goal is to

determine the range of possible effect sizes for a particular outcome measure rather than the effectiveness of a therapy for that disease manifestation. To avoid comparison among therapies, the resulting manuscript will report the trial datasets used but will de-identify the studies when reporting individual effect sizes. Pooled estimates (using meta-analytic methods) will be presented when applicable (if significant heterogeneity is not present – we hypothesize that there will be substantial heterogeneity that will prevent pooling).

Study Population
Patients with psoriatic arthritis.

Funding Source of Research
Rheumatology Research Foundation

Requested Study
IM101-332 (NCT01860976): Efficacy and Safety of Subcutaneous Abatacept in Adults With Active Psoriatic Arthritis (ASTRAEA)

IM101-158 (NCT00534313): Safety and Efficacy of Abatacept Versus Placebo in Participants With Psoriatic Arthritis