

# A Study to Evaluate the Impact of Upadacitinib on Spondyloarthritis Outcomes in Patients With Active Psoriatic Arthritis

NCT06454188

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Status	RECRUITING
Phase	Phase 4
Sponsor	CARE ARTHRITIS LTD.
Enrollment	100 participants

## Key Eligibility Criteria

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### Inclusion (40)

- Subject ≥18 of age at the screening visit.
- Subject must be able to understand and willing to adhere to all protocol requirements and voluntarily sign and date an informed consent, approved by an Independent Ethics Committee (IEC)/institutional review board (IRB), prior to the initiation of any screening or study-specific procedures.
- Diagnosis of PsA by their treating rheumatologist.
- Classification of PsA according to the CASPAR criteria: Inflammatory articular disease (joint, spine, or enthesal) AND at least 3 points of the following categories:
  - a) Evidence of psoriasis: (Score for one of the following) i) Current psoriasis - 2 points (Psoriatic skin or scalp disease present today as judged by a dermatologist or rheumatologist) ii) Personal history of psoriasis - 1 point (A history of psoriasis that may be obtained from the subject, family physician, dermatologist, rheumatologist, or other qualified health care provider) iii) Family history of psoriasis - 1 point (A history of psoriasis in a first- or second-degree relative according to subject report) b) Psoriatic nail dystrophy - 1 point i) Typical psoriatic nail dystrophy, including onycholysis, pitting, and hyperkeratosis, observed on current physical examination c) A negative test for rheumatoid factor - 1 point i) By any method except latex, but preferably by enzyme-linked immunosorbent assay (ELISA) or nephelometry, according to the local laboratory reference range d) Dactylitis: (Score for 1 of the following) i) Current dactylitis - 1 point (Swelling of an entire digit) ii) History of dactylitis - 1 point (A history of dactylitis recorded by a rheumatologist) e) Radiologic evidence of juxta-articular new bone formation - 1 point i) Ill-defined ossification near joint margins (but excluding osteophyte formation) on plain radiographs of the hand or foot.
- ... and 35 more (see full listing online)

### Exclusion (71)

- If subjects are currently taking bioDMARD therapy, they may be recruited after an appropriate wash-out period of bioDMARD prior to the screening MRI. Prior exposure to a bioDMARD is allowed for no more than 75 subjects, and prior exposure to a 2nd bioDMARD is allowed for no more than 30 subjects (one bioDMARD must include TNFi for US patients). Washout periods are as follows: 4 weeks for Etanercept, 8 weeks for Infliximab, 10 weeks for Adalimumab, Golimumab, Certolizumab and Ixekizumab, 12 weeks for Ustekinumab, Secukinumab, Guselkumab, and Abatacept, and 20 weeks for Risankizumab. However, subjects should not stop their previous successful biological therapy only to be included in this study. For patients intolerant to bioDMARD and not on such treatment a washout period may not be necessary.
- Active infection(s) requiring treatment with parenteral anti-infectives within 30 days, or oral anti-infectives within 14 days prior to the baseline Visit; Chronic recurring infection and/or active viral infection that based on the investigator's clinical assessment makes the subject an unsuitable candidate for the study.
- Confirmed COVID-19: the baseline visit must be at least 14 days from onset of signs/symptoms or positive SARS-CoV-2 test; symptomatic subjects must have recovered, defined as resolution of fever without use of antipyretics and improvement in symptoms;
- Suspected COVID-19: subjects with signs/symptoms suggestive of COVID-19, known exposure, or high-risk behavior should undergo molecular (e.g., PCR) testing to rule out SARS-CoV-2 infection or must be asymptomatic for 14 days from a potential exposure;
- History of recurrent (more than one episode) herpes zoster or disseminated/multi-dermatomal (a single episode) herpes zoster or disseminated (a single episode) herpes simplex.

... and 66 more (see full listing online)

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<https://clinicaltrials.gov/study/NCT06454188>

### Locations (5 total)

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University Hospitals Cleveland Medical Center, Cleveland, Ohio, United States  
Oregon Health and Science University, Portland, Oregon, United States  
University of Pennsylvania, Philadelphia, Pennsylvania, United States  
... and 2 more locations