Sponsor

UZ Gent
C. Heymanslaan 10
9000 Gent

SPARTACUS

Intake

Naam patient:

Geboortedatum:

Geslacht: ☐ man ☐ vrouw

Patient identificatiecode:

Behandelende arts:

Informed Consent Procedure

Patiënt kreeg info en uitleg door Dr. …….. op datum ……

Patiënt heeft uitgebreid tijd gehad voor vraagstelling? Ja / Nee

Patiënt kreeg antwoord op al zijn medische vragen door arts? Ja / Nee

Datum tekenen van Informed Consent: ……

Patiënt kreeg een kopie van het ICF mee Ja / Nee

Algemene opmerkingen:

……..

……

Inclusion Criteria

	Yes	**No**
Subject is able and willing to provide written informed consent and comply with the requirements of this study protocol.		
Subject is between 18 and 65 years of age.		
Subject was diagnosed with peripheral spondyloarthritis by the treating rheumatologist.		
Subject meets the ASAS classification criteria for peripheral spondyloarthritis		
ASAS Criteria : *At least one of the ASAS criteria must be selected to have an eligible patient. If not, please contact the PI.* ☐ Current arthritis ☐ Current enthesitis ☐ Current dactylitis		

At least 1 of the following SpA features. If not, please contact the PI.

☐ Anterior uveitis confirmed by an ophthalmologist (past or present)

☐ Crohn's disease or ulcerative colitis diagnosed by a gastroenterologist (past or present)

☐ Evidence of preceding infection (acute diarrhea or non-gonococcal urethritis or cervicitis 1 month before arthritis)

☐ Psoriasis (diagnosed by a dermatologist (past or present))

☐ HLA B27 positivity

☐ Sacroiliitis by imaging defined as bilateral grade 2-4 or unilateral grade 3-4 sacroiliitis on plain radiographs (according to the modified New York criteria or active sacroiliitis on MRI according to the ASAS consensus definition)

	Yes	**No**
Subject had onset of peripheral SpA symptoms ≤ 12 months prior to the screening visit		
Subject had active disease at screening defined by Patient Global Assessment of Disease Activity Numeric Rating Scale (NRS) ≥ 4 and Patient Global Assessment of Pain NRS ≥ 4.		
In case subject has concurrent axial SpA symptoms, the peripheral SpA symptoms are the predominant symptoms at study entry based on the Investigator's clinical judgement.		
Subject had a negative PPD test (or equivalent) and chest radiography (anteroposterior and lateral view) at screening. If the subject has a positive PPD test (or equivalent), has had a past ulcerative reaction following PPD placement and/or a chest radiography consistent with prior TB exposure, the subject will initiate, or has documented completion of a course of anti-TB therapy.		
In case subject is a woman of childbearing potential or a man capable of fathering children, adequate birth control measures will be used during the study and for 3 months after receiving the last administration of study agent.		
Subject is judged to be in good health as determined by the principal investigator based upon the results of medical history, physical examination, laboratory profile, and chest x-ray (CXR) performed during screening.		
Subject is able and willing to self-administer SC injections or have a qualified person available to administer SC injections.		

Exclusion Criteria

	Yes	No
Medical history of inflammatory arthritis of a different etiology than peripheral spondyloarthritis (e.g. rheumatoid arthritis, systemic lupus erythematosus, gout, ...)		
Prior adequate treatment with methotrexate and/or sulphasalazine		
Prior exposure to any biologic therapy with a potential therapeutic impact on SpA		
Treatment with any investigational drug of chemical or biological nature within a minimum of 30 days or 5 half-lives of the drug (whichever is longer) prior to the Baseline Visit		
Infection(s) requiring treatment with intravenous (iv) anti-infective agents within 30 days prior to the Baseline visit or oral anti-infectives within 14 days prior to the baseline Visit		
Subject is taking or has taken prohibited medications as outlined in Table 1 without meeting the mandatory washout period(s) relative to the baseline visit.		
Have a known hypersensitivity to human immunoglobulin proteins or other components of golimumab		
History of central nervous system (CNS) demyelinating disease or neurologic symptoms suggestive of CNS demyelinating disease		
History of listeriosis, histoplasmosis, chronic or active Hepatitis B infection, Hepatitis C infection, human immunodeficiency virus (HIV) infection, immunodeficiency syndrome, chronic recurring infections or active TB		
(History of) chronic heart failure, including medically controlled, asymptomatic CHF		
History of malignancy (including lymphoma and leukemia) other than a successfully treated non-metastatic cutaneous squamous cell or basal cell carcinoma or localized carcinoma in situ of the cervix		
Have received any live virus or bacterial vaccination within 3 months prior to the first administration of study agent; patients who are expected to receive such vaccinations during the trial, or within 3 months after the last administration of study agent		
Positive serum pregnancy test at screening		
Female subjects who is breast-feeding		
Clinically significant abnormal screening laboratory results as evaluated by the Investigator		

	Yes	**No**
Positive anti-cyclic citrullinated peptide (anti-CCP) antibody at screening if the titers are crossing 3 times the upper limit of normal		
Subject is considered by the investigator, for any reason, to be an unsuitable candidate for the study		
Subject with current symptoms of fibromyalgia that would confound evaluation of the patient		

Indien ja op één van voorgaande vragen-> geen inclusie!

Naam persoon die dit formulier ingevuld heeft: ……

Datum:……..

Naam en handtekening onderzoeker : ……..

Datum:……..