KURZPROTOKOLL
JWGKDVAAP0117

Öffentlicher Titel	Phase IV Studie zu Adalimumab bei aktiver, mittelschwerer-schwerer Hidradenitis suppurativa
Wissenschaftl. Titel	Exploratory study to evaluate changes in inflammatory pattern and analysis for serum biomarkers in patients with active, moderate-to-severe hidradenitis suppurativa after 2-week and 6-week treatment with a TNF-alpha Inhibitor
Kurztitel	JWGKDVAAP0117
Studienart	prospektiv, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase IV
Erkrankung	Haut: Acne inversa
Einschlusskriterien	- Diagnosis of HS for minimum of six months - Disease state diagnosed to be active and moderate to severe HS, requiring systemic therapy - No severe or otherwise clinically significant abnormalities found within the patient's medical/medication history, nor during physical examination - Minimum of one previously failed or insufficiently responded to systemic therapy for HS - Women of childbearing age who are sexually active must use a highly effective form of contraception (Pearl Index < 1%) for the duration of the study - Negative test for tuberculosis (TB) according to local guidelines, obtained no more than three months prior to screening - Written informed consent and availability of any locally required authorization obtained from the subject, prior to performing any protocol-related procedures - Patients must be able and willing to comply with the requirements of this protocol - Age 18–65 years
Ausschlusskriterien	- Main exclusion criteria: Previous use of Adalimumab (Humira®) or any other TNF-inhibitors - Exclusion criteria related to IMP: According to SmPC; According to approval status of EMA; According to approval status of Adalimumab for treatement of HS in Germany; Known hypersensitivity to any component of the IMP - Exclusion criteria related to general health: - Active dermatologic conditions that may confound the diagnosis of HS or would interfere with the assessment of treatment (e.g., atopic dermatitis, seborrhoic dermatitis, ichthyosis, psoriasis vulgaris, folliculitis) - History of a clinically significant infection four weeks prior to baseline visit, which, in the opinion of the investigator, may compromise the safety of the subject - History of chronic alcohol/drug abuse within the last 12 months before screening - Pregnant or breastfeeding women - Severe kidney insufficiency (GFR < 30 ml/min) - Any severe diseases that may, in the opinion of the investigator, interfere or worsen the hidradenitis suppurativa or result in safety concerns for patients being treated with an anti-TNF-alpha Inhibitor - History or presence of human immunodeficiency virus (HIV), and/or hepatitis B (HBV) or C virus (HCV) infections - History of active tuberculosis (TB), or untreated or inadequately treated latent TB (LTBI). Subjects must have a negative QuantiFERON, T-SPOT, or purified protein derivative (PPD) test, performed less than three months before the screening visit - Any active medication which suppresses the immune system - History, current signs, symptoms, or diagnosis of a demyelinating disorder

	- History of or current Class III or IV congestive heart failure, as defined by the New York Heart Association - History or current signs, symptoms, or diagnosis of lymphoproliferative disorders, lymphoma, leukemia, myeloproliferative disorders, or multiple myeloma - Current malignancy or history of any malignancy, except for adequately treated or excised non-metastatic basal cell or squamous cell cancer of the skin, or cervical carcinoma in situ; no more than a total of three lifetime basal cell or squamous cell carcinomas permitted - Concurrent enrolment in another clinical trial, in which the subject is receiving an investigational product - Any major surgery in the last four weeks, that in the opinion of investigator, study related procedures or treatment with an anti-TNF-alpha inhibitor is contraindicated - Severe, progressive, or uncontrolled renal, hepatic, metabolic, hematologic, gastrointestinal, endocrine, pulmonary, cardiac, or neurologic disease, including pleural effusions or ascites, which, in the opinion of the investigator pose an unacceptable safety risk - History of latex allergy
Alter	18 - 65 Jahre
Prüfzentren	**Klinik für Dermatologie, Venerologie und Allergologie** (Geschlossen) Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Andreas Pinter Tel: 069 6301-83115 Fax: 069 6301-83175 andreas.pinter@unimedizin-ffm.de
Sponsor	Goethe-Universität Frankfurt
Registrierung in anderen Studienregistern	EudraCT 2017-000435-13 (primäres Register)
Links	Zu den Ein- und Ausschlusskriterien