KURZPROTOKOLL
14V-MC-JAIP

Öffentlicher Titel	Phase III Studie zu Baricitinib bei Kindern mit moderater oder schwerer atopischer Dermatitis
Wissenschaftl. Titel	A Phase 3, Multicenter, Randomized, Double-blind, Placebo Controlled, Parallel-group, Out patient Study Evaluating the Pharmacokinetics, Efficacy and Safety of Baricitinib in Pediatric Patients with Moderate-to Severe Atopic Dermatitis
Kurztitel	14V-MC-JAIP
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, mehrarmig
Studienphase	Phase III
Erkrankung	Haut: Ekzem (Dermatitis): Neurodermitis (Atopische Dermatitis) Kinder: Hauterkrankungen
Einschlusskriterien	- At or above the 5th percentile of weight for age - Have been diagnosed with moderate to severe atopic dermatitis for at least 12 months (if 6 years old or older) or at least 6 months (if 2 up to 6 years old) - Have had inadequate response or intolerance to existing topical (applied to the skin) medications within 6 months preceding screening - Are willing to discontinue certain treatments for eczema (such as systemic and topical treatments during a washout period) - Agree to use emollients daily
Ausschlusskriterien	- Are currently experiencing or have a history of other concomitant skin conditions (e.g., psoriasis or lupus erythematosus), or a history of erythrodermic, refractory, or unstable skin disease that requires frequent hospitalizations and/or intravenous treatment for skin infections - A history of eczema herpeticum within 12 months, and/or a history of 2 or more episode of eczema herpeticum in the past - Participants who are currently experiencing a skin infection that requires treatment, or is currently being treated, with topical or systemic antibiotics - Have any serious illness that is anticipated to require the use of systemic corticosteroids or otherwise interfere with study participation or require active frequent monitoring (e.g., unstable chronic asthma) - Have been treated with the following therapies: Monoclonal antibody for less than 5 half-lives prior to beginning study treatment. Received prior treatment with any oral Janus kinase (JAK) inhibitor. Received any parenteral corticosteroids administered by intramuscular or intravenous (IV) injection within 2 weeks prior to study entry or within 6 weeks prior to planned initiation of study drug or are anticipated to require parenteral injection of corticosteroids during the study - Have had an intra-articular corticosteroid injection within 2 weeks prior to study entry or within 6 weeks prior to planned initiation of study drug - Have high blood pressure characterized by a repeated systolic or diastolic blood pressure >95th percentile based on age, sex and height - Have had major surgery within the past eight weeks or are planning major surgery during the study - Have experienced any of the following within 12 weeks of screening: venous thromboembolic event (VTE), myocardial infarction (MI), unstable ischemic heart disease, stroke, or New York Heart Association Stage III/IV heart failure - Have a history of VTE or are considered at high risk of VTE as deemed by the investigator - Have a history or presence of cardiovascular, respiratory, hepatic, chronic liver disease gastrointestinal, endocrine, hematological, neurological, lymphoproliferative disease or neuropsychiatric disorders or any other serious and/or unstable illness

	- Have a current or recent clinically serious viral, bacterial, fungal, or parasitic infection including herpes zoster (shingles or chicken pox), tuberculosis - Have specific laboratory abnormalities - Have received certain treatments that are contraindicated - Pregnant or breastfeeding
Alter	2 - 17 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	Eli Lilly and Company
Registrierung in anderen Studienregistern	EudraCT 2018-000349-38 ClinicalTrials.gov NCT03952559 (primäres Register)