

## **KURZPROTOKOLL** **14V-MC-JAIP**

<b>Öffentlicher Titel</b>	Phase III Studie zu Baricitinib bei Kindern mit moderater oder schwerer atopischer Dermatitis
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	14V-MC-JAIP
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, mehrarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Haut: Ekzem (Dermatitis): Neurodermitis (Atopische Dermatitis) Kinder: Hauterkrankungen
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- At or above the 5th percentile of weight for age</li><li>- 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)</li><li>- Have had inadequate response or intolerance to existing topical (applied to the skin) medications within 6 months preceding screening</li><li>- Are willing to discontinue certain treatments for eczema (such as systemic and topical treatments during a washout period)</li><li>- Agree to use emollients daily</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- 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</li><li>- A history of eczema herpeticum within 12 months, and/or a history of 2 or more episode of eczema herpeticum in the past</li><li>- Participants who are currently experiencing a skin infection that requires treatment, or is currently being treated, with topical or systemic antibiotics</li><li>- 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)</li><li>- 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</li><li>- 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</li><li>- Have high blood pressure characterized by a repeated systolic or diastolic blood pressure &gt;95th percentile based on age, sex and height</li><li>- Have had major surgery within the past eight weeks or are planning major surgery during the study</li><li>- 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</li><li>- Have a history of VTE or are considered at high risk of VTE as deemed by the investigator</li><li>- 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</li></ul>

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- 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)**  
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