# *KURZPROTOKOLL*
# *RIG-P000814*

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| **Öffentlicher Titel** | Phase II Studie zu Ruxolitinib bei Steroid-refraktärer akuter Graft-vs-Host Erkrankung |
| **Wissenschaftl. Titel** | Multicenter, randomzied Phase 2 trail to determine the Response Rate of Ruxolitinib and Best Available Treatment (BAT) versus BAT in Steroid refractory acute Graft-versus-host Disease (aGvHD) |
| **Kurztitel** | RIG-P000814 |
| **Studienart** | multizentrisch, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, kontrolliert, Investigator Initiated Trial (IIT) |
| **Studienphase** | Phase II |
| **Erkrankung** | Blut: Stammzelltransplantation: Transplantat-gegen-Wirt-Reaktion (GvHD) |
| **Einschlusskriterien** | - Acute skin, intestinal or liver GvHD > grade 1 according to standard criteria<br>- Histological confirmation in case of acute intestinal GvHD<br>- Age >=18 years<br>- Failure of previous treatment, defined as presence of at least one of the following criteria:<br>- a. Treatment with prednisone/prednisolone/methylprednisolone in a dose of at least 2 mg/kg and lack of response after at least 7 days treatment<br>- b. Treatment with prednisone/prednisolone/methylprednisolone in a dose of at least 2 mg/kg and progression after at least 3 days of treatment<br>- c. Failure to taper the prednisone/prednisolone to 0.6 mg/kg/day or methylprednisolone dose to <0.5 mg/kg/day<br>- Written informed consent<br>- Ability to understand the nature of the study and the study related procedures and to comply with them |
| **Ausschlusskriterien** | - Uncontrolled underlying disease<br>- Active bleeding<br>- Absence of clinical signs of acute GvHD<br>- Diagnostic or distinctive clinical signs of chronic GvHD<br>- Uncontrolled bacterial, viral or fungal infection<br>- Any previous JAK2 inhibitor treatment prior to study enrolment, except Ruxolitinib given prior to the allogeneic stem cell transplantation<br>- Known Hypersensitivity to Ruxolitinib or any of the excipients<br>- Known positivity for HIV, Hepatitis B or Hepatitis C at the time of screening.<br>- Female patients who are pregnant or breast feeding<br>- Concomitant use of any other investigational drug within the last thirty days before the start of this study |
| **Alter** | 18 Jahre und älter |
| **Prüfzentren** | **Universitätsklinikum Gießen und Marburg, Standort Marburg** (Rekrutierung beendet)<br>Hämatologie, Onkologie und Immunologie<br>Baldingerstraße<br>35043 Marburg<br>Sandra Winter<br>Tel: 06421 58 63732<br>Fax: 06421 58 63175<br>Sandra.Winter@uk-gm.de |
| **Sponsor** | Universitätsklinikum Freiburg |
| **Förderer** | Deutsche Krebshilfe e.V. |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT02396628 (primäres Register)<br>EudraCT 2014-004267-20 |