KURZPROTOKOLL
RIG-P000814

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 - Histological confirmation in case of acute intestinal GvHD - Age >=18 years - Failure of previous treatment, defined as presence of at least one of the following criteria: - 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 - b. Treatment with prednisone/prednisolone/methylprednisolone in a dose of at least 2 mg/kg and progression after at least 3 days of treatment - c. Failure to taper the prednisone/prednisolone to 0.6 mg/kg/day or methylprednisolone dose to <0.5 mg/kg/day - Written informed consent - Ability to understand the nature of the study and the study related procedures and to comply with them
Ausschlusskriterien	- Uncontrolled underlying disease - Active bleeding - Absence of clinical signs of acute GvHD - Diagnostic or distinctive clinical signs of chronic GvHD - Uncontrolled bacterial, viral or fungal infection - Any previous JAK2 inhibitor treatment prior to study enrolment, except Ruxolitinib given prior to the allogeneic stem cell transplantation - Known Hypersensitivity to Ruxolitinib or any of the excipients - Known positivity for HIV, Hepatitis B or Hepatitis C at the time of screening. - Female patients who are pregnant or breast feeding - 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) Hämatologie, Onkologie und Immunologie Baldingerstraße 35043 Marburg Sandra Winter Tel: 06421 58 63732 Fax: 06421 58 63175 Sandra.Winter@uk-gm.de
Sponsor	Universitätsklinikum Freiburg
Förderer	Deutsche Krebshilfe e.V.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02396628 (primäres Register) EudraCT 2014-004267-20