

KURZPROTOKOLL
RIG-P000814

Öffentlicher Titel	Phase II Studie zu Ruxolitinib bei Steroid-refraktärer akuter Graft-vs-Host Erkrankung
Wissenschaftl. Titel	Multicenter, randomizied 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
Sponsor	Universitätsklinikum Freiburg
Förderer	Deutsche Krebshilfe e.V.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02396628 (primäres Register) EudraCT 2014-004267-20