## KURZPROTOKOLL CLL 13

Öffentlicher Titel         Phase-III-Studie für CLL-Patienten ohne del(17p) oder TPS3 Mutationen, die eine von vier Kombinatonsherapiena zur Estimienbehandung erhalten: Standardhemoimmunberapie, Rituzinimab + Venetoclax, Obinutuzumab + Venetoclax oder Obinutuzumab + Ibrutinib + Venetoclax, Obinutuzumab y Venetoclax (GNO) versus obinutuzumab (GNO10) plus versus obinutuzumab (GNO10) plus versus obinutuzumab (GNO10) plus versus obinutuzumab (CLL) without del(17p) or TPS3 mutation           Kurzitiel         CLL 13           Studienphase         Phase III           Erischlusskriterien         Diet Studienphase           Einschlusskriterien         Ability and willingness to provide written informed consent and to ad-here to the study visit schedule and other protocol requirements.           Adequate bone marrow function indicated by a platelet count >30 x10/91 (unless directly attributable to CLL influration of the bone marrow proven by bone marrow biopsy)           Creatinine clearance 70m/min directly measured with 24hr urine collection or calculated according to the modified formula of Cackord and Gault (or men: GFR (174) - age) stoleter function as indicated by a total biltrution 2, x5T/ALT 2, 5 x the institutional ULV value, unless directly attributable to CLL influration of the patient is 2, a marrow biopsy)           Creatinine clearance 70m/min directly measured with 24hr urine collection or calculated according to the modified formula of Cackord and Gault (for men: GFR (174) - age) x bodyweight) / 172 x creatining, for women x 0, 86, Dehydrated plates with a status 0/2, negative and anti-HBC negative: patients with an estimated for readquate hydrotion is 7 m (minin 2, 2, 5 x the institutional ULV value, unless directly attributable to the patient's CLL or to Gi			
<ul> <li>chemoimmunotherapy (FCR/BR) versus fituximab plus venetockax (GV) versus obinutuzumab plus inclutuable plus inclutable plus include plus inclutuable plus inclutable plus inclutuable plus plus inclutuable plus inclutuable plus inclutuable plus inclu</li></ul>	Öffentlicher Titel	vier Kombinationstherapien zur Erstlinienbehandlung erhalten: Standardchemoimmuntherapie, Rituximimab + Venetoclax, Obinutuzumab + Venetoclax	
Studienart       multizentrisch, Therapiestudie, offen/unverblindet, mehrarmig         Studienphase       Phase III         Erkrankung       Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: Chronische lymphatische Leukämie (CLL) - neu diagnostiziert / de novo         Einschlusskriterien       - 1. Documented CLL requiring treatment according to iwCLL criteria12.         Age at least 18 years.       - Life expectancy 6 months.         Ability and willingness to provide written informed consent and to ad-here to the study visit schedule and other protocol requirements.         Adequate bone marrow function indicated by a platelet count >30 x10^9/l (unless directly attributable to CLL infiltration of the bone marrow, proven by bone marrow biopsy)         Creatinine clearance 20ml/min directly measured with 24hr urine collection or calculated according to the modified formula of Cockcroft and Gault (for men: GFR ((140 - age) x bodyweight) /(72 x creatinine), for women x0, 83b, Dehydrated patents with an estimated creatinine clearance less than 70 m/min may be eligible if a repeat estimate after adequate hydration is > 70 m/min.         Adequate liver function as indicated by a total bilirubin 2 x. AST/LT 2.5 x the institutional ULN value, unless directly attributable to the patient's CLL or to Gilbert's Syndrome.         Ausschlusskriterien       - Regative serological testing for hepatitis C RNA within 6 weeks prior to registration.         E astern Cooperative Oncology Group Performance Status (ECOG) performance status 0-2.       - Transformation of CLL (Richter transformation).         Deecompensated hemolysis, defined as ongoing hemoglo	Wissenschaftl. Titel	chemoimmunotherapy (FCR/BR) versus rituximab plus ve-netoclax (RVe) versus obinutuzumab (GA101) plus venetoclax (GVe) versus obinutuzumab plus ibrutinib plus venetoclax (GIVe) in fit pa-tients with previously untreated chronic lymphocytic leukemia	
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## KURZPROTOKOLL CLL 13

- Urinary outflow obstruction.
- Malignancies other than CLL currently requiring systemic therapies, not being treated in curative intention before (unless the malignant disease is in a stable remission due to the discretion of the treating physician) or showing signs of progression after curative treatment.
- Uncontrolled or active infection.
- Patients with known infection with human immunodeficiency virus (HIV).
- Requirement of therapy with strong CYP3A4 and CYP3A5 inhibi-tors/inducers.
- Anticoagulant therapy with warfarin or phenoprocoumon, (rotation to alternative anticoagulation is allowed, but note that patients being treated with NOAKs can be included, but must be properly informed about the potential risk of bleeding under treatment with ibrutinib).
- History of stroke or intracranial hemorrhage within 6 months prior to registration.
- Use of investigational agents which might interfere with the study drug within 28 days prior to registration.
- Vaccination with live vaccines 28 days prior to registration.
- Major surgery less than 30 days before start of treatment.
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies, known sensitivity or allergy to murine products.
- Known hypersensitivity to any active substance or to any of the excipients of one of the drugs used in the trial.
- Pregnant women and nursing mothers (a negative pregnancy test is required for all women of childbearing potential within 7 days before start of treatment; further pregnancy testing will be performed regularly).
- Fertile men or women of childbearing potential unless: a. surgically sterile or 2 years after the onset of menopause b. willing to use two methods of reliable contraception including one highly effective contraceptive method (Pearl Index <1) and one additional effective (barrier) method during study treatment and for 18 months after the end of study treatment.
- Legal incapacity.
- Prisoners or subjects who are institutionalized by regulatory or court order.
- Persons who are in dependence to the sponsor or an investigator.

Alter	18 Jahre und älter
Fallzahl	920
Sponsor	Universität Köln
Registrierung in anderen	ClinicalTrials.gov NCT02950051
Studienregistern	EudraCT 2015-004936-36