

KURZPROTOKOLL
AVOID-XM22-ONC-305

Öffentlicher Titel	Phase IIb Studie zu Lipegfilgrastim im Vergleich zu Pegfilgrastim bei Non-Hodgkin Lymphomen
Wissenschaftl. Titel	A randomized, phase IIb, open-label, two-arm, multicenter, comparative study on efficacy and safety of lipegfilgrastim (Lonquex, TEVA) in comparison to pegfilgrastim (Neulasta, Amgen) in elderly patients with aggressive B cell Non-Hodgkin lymphomas at high risk for R-CHOP-21-induced neutropenia – AVOID Neutropenia
Kurztitel	AVOID-XM22-ONC-305
Studienart	multizentrisch, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), hoch-maligne: Neu diagnostiziert / de novo
Einschlusskriterien	<ul style="list-style-type: none">- Signed and dated Independent Ethics Committee (IEC)-approved written informed consent- Age 65 years and 85 years- Histological documentation of aggressive B cell Non-Hodgkin Lymphoma- Planned to receive systemic anticancer therapy with at least 6 cycles of R-CHOP-21, according to local standards- Eastern Cooperative Oncology Group (ECOG) score 2- Life expectancy of at least 3 months- Adequate bone marrow, renal and hepatic function as evidenced by the following within 14 days before start of chemotherapy: - absolute neutrophil count (ANC) $1.5 \times 10^9/L$ - platelets $100 \times 10^9/L$ - hemoglobin 9.0 g/dL - serum creatinine 1.5 x upper limit of the normal range (ULN) OR glomerular filtration rate (GFR) 30 mL/minute/1.73 m² - AST and ALT 2.5 x ULN; bilirubin 1.5 x ULN; alkaline phosphatase limit 2.5 x ULN- The patient is capable of understanding and complying with parameters as outlined in the protocol.- Women of childbearing potential (not surgically sterile or 2 years postmenopausal) must use a medically accepted method of contraception and must agree to continue use of this method for the duration of the treatment and for 30 days after discontinuation of study drug. Acceptable methods of contraception include intrauterine device (IUD), steroidal contraceptive (oral, implanted, transdermal, or injected), barrier method with spermicide, abstinence, and partner vasectomy.- The patient, if a man, is surgically sterile, or, if capable of producing offspring, is currently using an approved method of birth control and agrees to continued use of this method for the duration of the treatment (and for 90 days after taking the last dose of study drug because of the possible effects on spermatogenesis). Acceptable methods of contraception include abstinence, female partner's use of an acceptable method of contraception (described above), or if female partner is surgically sterile or 2 years post-menopausal. In addition, male patients may not donate sperm for the duration of the study and for 90 days after taking study drug.
Ausschlusskriterien	<ul style="list-style-type: none">- Participation in a clinical study within 30 days before randomization- Any chemotherapy within the last 3 months before start of chemotherapy. A prephase to reduce tumor burden prior to start of R-CHOP is allowed.- The patient is a pregnant or lactating woman. (Any woman becoming pregnant during the study will be withdrawn from the study.)- Major surgical procedure, open biopsy, or significant traumatic injury within 28 days before start of chemotherapy.

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- Active cardiac disease including any of the following: Congestive heart failure New York Heart Association (NYHA) class 2; Unstable angina, new-onset angina, myocardial infarction less than 6 months before start of chemotherapy; Cardiac arrhythmias requiring anti-arrhythmic therapy (beta blockers or digoxin are permitted); Uncontrolled hypertension.
- Arterial or venous thrombotic or embolic events such as cerebrovascular accident (including transient ischemic attacks), deep vein thrombosis or pulmonary embolism within 6 months before start of chemotherapy.
- Ongoing infection, known history of human immunodeficiency virus (HIV) infection, tuberculosis, or chronic hepatitis B or C.
- Patients with evidence or history of bleeding diathesis.
- Non-healing wound, ulcer or bone fracture.
- Renal failure requiring hemo- or peritoneal dialysis.
- Any conditions that may interfere with the patient's participation in the study or evaluation of the study results.
- Known hypersensitivity to any of the study drugs, study drug classes, or excipients in the formulation.
- Any illness or medical conditions that are unstable or could jeopardize the safety of the patient and his/her compliance in the study.
- Treatment with lithium at screening or planned during the study.

Alter	65 Jahre und älter
Sponsor	Merckle GmbH
Registrierung in anderen Studienregistern	EudraCT 2013-001284-23