

KURZPROTOKOLL
EsPhALL2017

Öffentlicher Titel	Phase III Studie zu Imatinib + Chemotherapie bei Philadelphia-positiver ALL
Wissenschaftl. Titel	International phase 3 trial in Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) testing imatinib in combination with two different cytotoxic chemotherapy backbones
Kurztitel	EsPhALL2017
Studienart	prospektiv, Therapiestudie, randomisiert, offen/unverblindet, dreiarmlig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Kinder: Leukämien und Lymphome: Neu diagnostiziert / de novo
Einschlusskriterien	- Newly diagnosed de novo ALL (B-ALL or T-ALL) with definitive evidence of BCR-ABL1 fusion by karyotype, FISH and/or RT-PCR - Adequate liver, cardiac, renal function
Ausschlusskriterien	- Known history of chronic myelogenous leukemia (CML) - ALL developing after a previous cancer treated with cytotoxic chemotherapy - Active, uncontrolled infection or active systemic illness that requires ongoing vasopressor support or mechanical ventilation - Down syndrome - Pregnancy and Breast Feeding - Patients with congenital long QT syndrome, history of ventricular arrhythmias or heart block - Prior treatment with dasatinib, or any BCR-ABL1 inhibitor other than imatinib.
Alter	1 - 20 Jahre
Molekularer Marker	BCR-ABL1
Prüfzentren	Universitätsmedizin Frankfurt (Nachbeobachtung) Klinik für Kinder- und Jugendmedizin Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med. Thomas Lehrnbecher Tel: 069 6301-6489 Fax: 069 6301-6009 thomas.lehrnbecher@unimedizin-ffm.de
Sponsor	Università degli Studi Milano Bicocca