Schweizerische Pädiatrische Onkologie Gruppe
Groupe d'Oncologie Pédiatrique Suisse
Gruppo d'Oncologia Pediatrica Svizzera
Swiss Paediatric Oncology Group

# IntReALL HR 2010

**Background**

Acute lymphoblastic leukaemia, ALL for short, is the most common form of blood cancer in children and adolescents. The disease begins in the bone marrow, where the normal process of blood formation is disrupted by the uncontrolled proliferation of immature blood cells. Untreated, ALL leads to serious illness and impairment of the organs with a fatal outcome. The majority of ALL patients can be cured with the current standard therapy. But in 15-20% of ALL patients, the leukaemia recurs in spite of the initial treatment, worsening the prognosis and making further treatment necessary. The Charité-Universitätsmedizin in Germany is responsible for the international implementation of the study (sponsor). In Switzerland, the Swiss Paediatric Oncology Group (SPOG) is responsible for the conduct of the study (sponsor representative).

**Why does the trial need to be done?**

The treatment concept of this trial is designed for children and adolescents with recurrent ALL who are in the high-risk group and therefore have the least favourable prognosis. The trial will investigate the efficacy of the new medicine bortezomib. Together with other medicines, bortezomib can prevent the cancer cells from multiplying and lead to their death. The aim of the trial is therefore to test whether bortezomib in conjunction with the standard therapy works better than the standard therapy alone and is therefore able to improve treatment outcomes in children and adolescents. Participating patients will be assigned randomly to one of two groups and will be given either the standard therapy on its own or with the additional administration of bortezomib. If a possible advantage for one of the two groups should emerge following one of the interim evaluations planned during the trial, more patients will be assigned to the possibly more advantageous trial group. If one group turns out to be definitely superior or inferior, the assignment of patients will be stopped and all patients will be given the therapy that has proven to be superior.

**Contact details for the sponsor representative in Switzerland:**
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