



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

ML-DS 2018

The Society of Paediatric Oncologists and Haematologists (GPOH) in Germany is responsible for the international implementation of the trial (sponsor). The Swiss Paediatric Oncology Group (SPOG) is responsible for performing the trial in Switzerland (sponsor representative).

Background:

Myeloid leukaemia (ML) is a rare blood cancer in children and adolescents that affects the whole body. Children with Down syndrome (DS) are at substantially increased risk of developing myeloid leukaemia. While they have a better prognosis compared to children without Down syndrome, these patients tend to have greater side effects from the intensive chemotherapy. In light of this, children with ML-DS require special treatment. About three children and adolescents in Switzerland are affected by this disease annually and can take part in the ML-DS 2018 trial.

Why does the trial need to be done?

The medicinal product Vyxeos is administered in the first half of this trial, in contrast to standard treatment. Vyxeos is already authorised for the treatment of myeloid leukaemia in adults and has shown promising outcomes. The medicinal product is not yet authorised for children, although it has already been used successfully in trials in children with leukaemia. This is the first trial in which Vyxeos is being used in children with Down syndrome and ML.

In addition to the standard treatment, the trial also measures the number of remaining leukaemia cells in the blood and bone marrow during treatment. This trial is intended to estimate the likelihood of the illness returning after treatment and contributes to treatment planning. A reduced medication dose compared to the standard treatment is selected in the trial towards the end of treatment for children with a low probability of recurrence.

To correctly assess the efficacy and safety of the trial treatment in all details, a standardised diagnostic workup is performed in the reference laboratories and medical data from all participating patients is recorded, stored and evaluated together.

Contact details for the sponsor representative in Switzerland:

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