Exploration of the intracellular pharmacokinetics of decitabine in patients with leukemia or myelodysplasia – A pilot study

The present study will be focused on exploring the intracellular pharmacokinetics of decitabine. Special attention will be given to the amount of genomic DNA incorporated decitabine, as it will be the first time this analysis will be performed in patient material. Furthermore, intracellular concentrations of decitabine and decitabine phosphates will be determined as well (as previously investigated). Finally, the methylation grade of the isolated genomic DNA will be assessed to see if there is a connection between the amount of decitabine that is incorporated, and the methylation grade of the DNA.

Study design:

Observational study.

Study population:

In subjects (>18 years of age) diagnosed with AML or MDS who are treated with 10-days decitabine, additional whole blood samples will be collected on day 1, day 5 and day 10 of the same decitabine treatment cycle. Patients will be approached for the first 2 cycles of decitabine.

Inclusion criteria

- Diagnosed AML or MDS according to WHO guidelines -≥18 years
- Planned for treatment start with decitabine (ten-day cycle)

Exclusion criteria

- Age < 18 years

Main study parameters/endpoints:

To determine the intracellular concentrations of decitabine, decitabine phosphates and genomic DNA incorporated decitabine. Peripheral Blood Mononuclear Cells (PBMCs) will be isolated from whole blood as a surrogate marker for intracellular assessments.