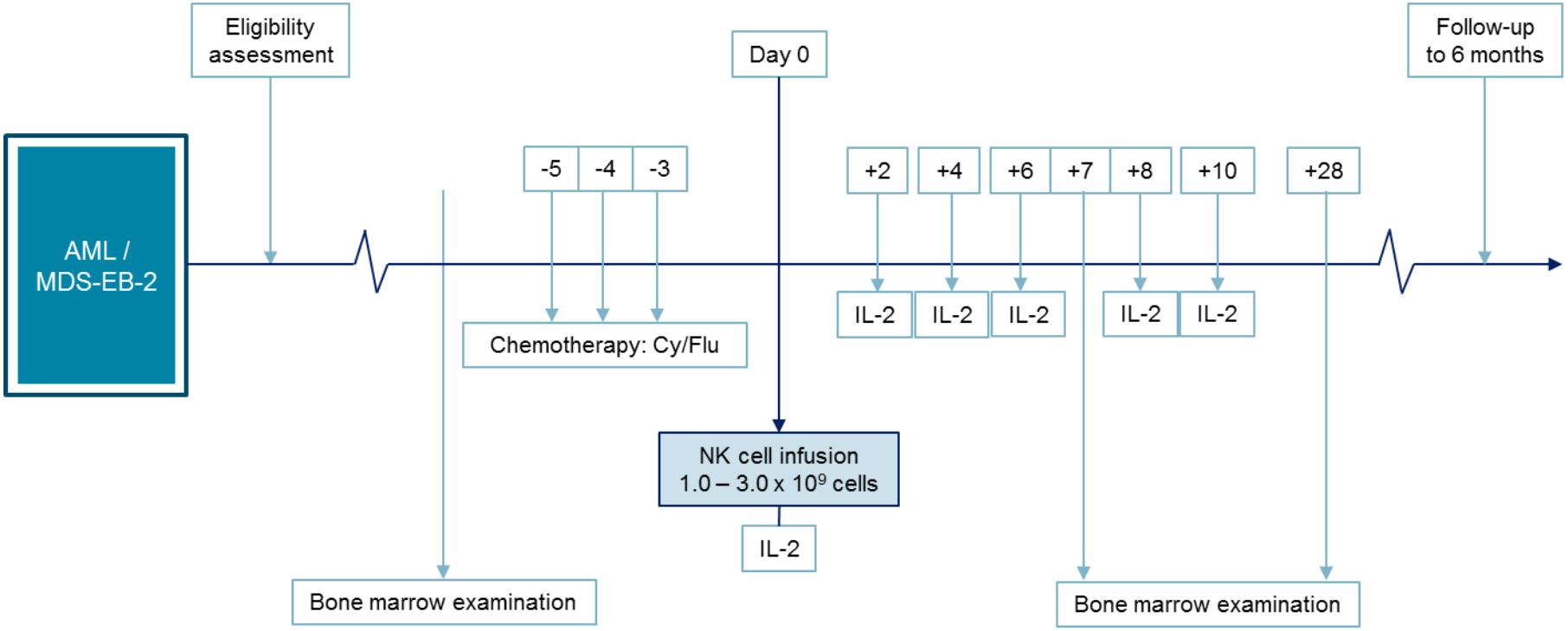
NK4AML

Study design

In- and exclusion criteria

Radboudumc

Treatment schedule



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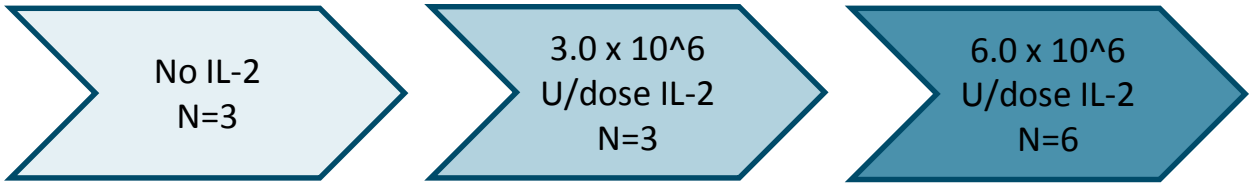
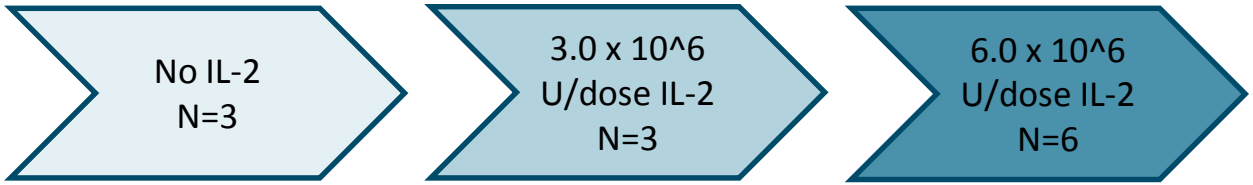
Study design

Phase 1: safety and toxicity



Study design

Phase 1: safety and toxicity



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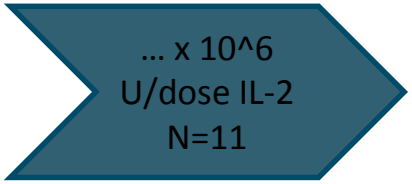
Phase 2: clinical efficacy



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Inclusion criteria

- Newly diagnosed AML or MDS EB-2 (WHO 2016); AML may be secondary to prior hematological disorders, including MDS, and/or therapy related
- Stable or at least non-rapidly progressive disease with or without disease controlling medication

Patients may belong to any of the following categories:

- Relapsed or refractory disease after treatment with intensive chemotherapy, hypomethylating agents, targeted agents, autologous or allogeneic SCT (at least 6 months ago) and DLI
- Newly diagnosed, untreated patients ineligible for allo-SCT

Inclusion criteria

- AML or MDS EB-2 (WHO 2016)
- Stable or at least non-rapidly progressive disease with or without disease controlling medication

- Age ≥ 18 years
- WHO performance 0 - 2
- Life expectancy of > 4 months
- Written informed consent
- Hydrea is allowed as pre-treatment to control blast count until day -3
- Hypomethylating agents decitabine or azacitidine are allowed until day -7

Exclusion criteria

- Rapid-progressive disease (in case of previous therapy)
- Patients on immunosuppressive drugs or active GvHD
- Patients with active infections (viral, bacterial or fungal); acute anti-infectious therapy must have been completed within 14 days prior to study treatment
- Severe cardiovascular disease, pulmonary, renal, hepatic, neurological or psychiatric dysfunction (CTCAE III-IV)
- Presence of anti-HLA class I antibodies
- Patients on concurrent chemotherapy or interferon-alpha treatment
- Pregnancy or breastfeeding