

SAMENVATTING HOVON 146

TITEL: Blinatumomab added to prephase and consolidation therapy in precursor B-acute lymphoblastic leukemia in adults. A phase II trial

INDICATIE : Adult patients, 18 to 70 years of age, with precursor B-ALL

SCHEMA: Zie laatste pagina.

INCLUSIE CRITERIA

- Primary CD19 positive precursor B-ALL (excluding mature B-cell ALL and B-lymphoblastic lymphoma, but including Philadelphia positive/BCR-ABL positive ALL) and CD19 positive mixed phenotype acute lymphoblastic leukemia (MPAL);
- Patients aged 18 to 70 years inclusive;
- WHO performance status 0-2;
- Negative pregnancy test at inclusion, if applicable;
- Written informed consent;
- Patient is capable of giving informed consent.

EXCLUSIE CRITERIA

- Mature B-cell leukemia/lymphoma, B-lymphoblastic lymphoma, isolated extramedullary disease;
- CML in blast crisis;
- Acute undifferentiated leukemia;
- Previous treatment with chemotherapy for precursor B-ALL (maximum 5 days of steroid treatment is allowed)
- Persistent liver enzyme disorders (ASAT/ALAT) >5xULN despite steroid pre-treatment (see also 8.1.3.)
- Severe cardiovascular disease (arrhythmias requiring chronic treatment, congestive heart failure or symptomatic ischemic heart disease);
- Severe pulmonary dysfunction (CTCAE grade III-IV, see appendix D);
- Severe neurological or psychiatric disease;
- Active, uncontrolled infection;
- Clinically overt central nervous system disease;
- History of active malignancy during the past 5 years with the exception of basal cell carcinoma of the skin or stage 0 cervical carcinoma;
- Patient known to be HIV-positive;
- Pregnant or breast-feeding female patients;
- Unwilling or not capable to use effective means of birth control (all men, all premenopausal women under the age of 50 need contraception for two years after the last period, and women older than 50 years for at least one year);
- Current participation in another clinical trial;
- Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule.

SCHEMA

