GIMEMA AML1819

Phase III study to assess the impact of gemtuzumab ozogamicin, in combination with standard chemotherapy, on the levels of minimal residual disease, in adult patients, aged 18-60 years, with previously untreated, de novo, favorable-intermediate-risk acute myeloid leukemia

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Trattamento: gemtuzumab ozogamicin,

Sindromi target: acute myeloid leukemia

Principali Criteri Inclusione:

1. Patients aged between 18 and 60 years.
2. Patients previously untreated for their AML by other chemotherapeutic agents (except for no more than 14 days HU) or radiotherapy.
3. Unequivocal diagnosis of de novo AML according to WHO diagnostic criteria (at least 20% blasts in the bone marrow), other than acute promyelocytic leukemia, documented by bone marrow aspiration (or biopsy in case of dry tap) (not supervening after other myeloproliferative disease or myelodysplastic syndromes of ≥ 6 months duration).
4. Patients with favorable-intermediate AML according to ELN 2017 (except for FLT3-ITD/TKD positive AML).
5. WHO performance status 0-3.
6. Adequate renal (serum creatinine ≤ 2 x the institutional ULN) and liver (total serum bilirubin ≤ 2 x ULN; serum ALT and AST ≤ 2.5 x ULN) function, unless considered due to organ leukemic involvement.
7. Left Ventricular Ejection Fraction (LVEF) ≥ 50%, as determined by echocardiogram
8. Absence of severe concomitant neurological or psychiatric diseases and congestive heart failure or active uncontrolled infection.
9. Absence of any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and the follow-up schedule.

Principali Criteri Esclusione:

2. Acute promyelocytic leukemia

3. Blast crisis of chronic myeloid leukemia

4. FLT3-ITD/TKD positive AML

5. AML supervening after other myeloproliferative disease

6. AML supervening after antecedent myelodysplastic syndromes ≥ 6 months duration

7. Therapy-related AML

8. Other active or progressive malignant diseases.