Reduced intensity chemotherapy given with and without Imatinib Mesylate in patients >= 60 years considered unfit for standard chemotherapy with previously untreated Acute Myeloid Leukemia (AML) and refractory anemia with excess of Blasts (RAEB, RAEB-T); A randomized phase II study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25417

Source
NTR

Brief title
HOVON / SAKK AML - 67

Health condition

AML

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
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Source(s) of monetary or material Support: HOVON is supported by the Dutch Cancer Society.

Intervention

Outcome measures

Primary outcome

CR rate.

Secondary outcome

1. Overall survival (time from registration till the death of the patient.);

2. Event free survival (i.e., time from registration to induction failure, death or disease progression, whichever occurs first);

3. Adverse events / toxicity.

Study description

Background summary

Study phase:

Phase II.

Study objective:

Evaluation of the effect of imatinib on efficacy of reduced intensity induction and consolidation chemotherapy in AML patients >= 60 years considered unfit for standard chemotherapy.

Patient population:

Patients with AML (except FAB M3), RAEB or RAEB-T with an IPSS score of > 1.5.

Study design:

Prospective, multicenter, randomized
Duration of treatment: From 4 weeks till 40 weeks dependent on response and whether or not allocated to receive treatment with imatinib.

Study objective

The hypothesis to be tested is that the outcome in arm 2 is better than in arm 1.

Study design

N/A

Intervention

The reduced intensity chemotherapy will consist of one induction cycle (cycle I) followed by one cycle of consolidation (cycle II).

The chemotherapy regimen for induction is as follows:

-Ara-C 100 mg/m2/day iv continuous infusion, days 1-5;

-Daunorubicin (DNR) 45 mg/m2/day iv 3h, days 1-2;

The chemotherapy regimen for consolidation is as follows:

-Ara-C 100 mg/m2/day iv continuous infusion, days 1-5;

-Daunorubicin (DNR) 45 mg/m2/day iv 3h, days 1-2;

Patients assigned to the imatinib arm, in addition will receive a daily dose of 600 mg imatinib p.o. from day 1 of the chemotherapy cycle till the end of week 40 (or until disease progression (death), or in case of no CR or no PR after cycle I or II.)

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients >= 60 years;

2. Patients considered unfit for standard chemotherapy;

3. Patients with a confirmed diagnosis of:

a. AML FAB M0-M2 or M4–M7 (see appendix A);

b. with refractory anemia with excess of blasts (RAEB) or refractory anemia with excess of blasts in transformation (RAEB-T) with an IPSS score >= 1.5;

4. Subjects with secondary AML progressing from antecedent (at least 4 months duration) myelodysplasia are also eligible;

5. AST (SGOT) and ALT (SGPT), total serum bilirubin, serum creatinine, and creatinine clearance not more than 1.5 x the upper limit of the normal range (ULN) at the laboratory where the analyses were performed;

6. Male patients agree to employ an effective barrier method of birth control throughout the study and for up to 3 months following the discontinuation of study drug;

7. Written informed consent.

Exclusion criteria

1. Patients previously treated for AML (any antileukemic therapy including investigational agents);

2. Patients with cardiac dysfunction as defined by:

a. Myocardial infarction within the last 6 months prior to study entry;

b. Reduced left ventricular ejection fraction of < 50% as evaluated by echocardiogram or MUGA scan;

c. Unstable angina;

d. Unstable cardiac arrhythmia;

3. Patients with a history of non-compliance to medical regimens or who are considered potentially unreliable;

4. Patients with any serious concomitant medical condition, which could, in the opinion of the investigator, compromise participation in the study;

5. Patients who have senile dementia, mental impairment or any other psychiatric disorder that prohibits the patient from understanding and giving informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2006
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion Date:	01-05-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL599
NTR-old	NTR655
Other	: HO67
ISRCTN	ISRCTN70542454

Study results

Summary results
N/A