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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), refractory anemia with excess blasts in transformation (RAEB-T): a randomized phase II study

Submission date 07/06/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 07/06/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/06/2006	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hovon.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HO67

Study information

Scientific Title

Acronym
HOVON / SAKK AML - 67

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized phase II study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute myeloid leukemia (AML)

Interventions
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:
1. Ara-C 100 mg/m^2/day continuous intravenous (iv) infusion, days 1-5
2. Daunorubicin (DNR) 45 mg/m^2/day iv 3h, days 1-2

The chemotherapy regimen for consolidation is as follows:
1. Ara-C 100 mg/m^2/day iv continuous infusion, days 1-5
2. Daunorubicin (DNR) 45 mg/m^2/day iv 3h, days 1-2

Patients assigned to the imatinib arm, in addition will receive a daily dose of 600 mg imatinib orally (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 complete remission (CR) or no partial remission (PR) after cycle I or II.)

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Imatinib mesylate

Primary outcome measure
Complete remission (CR) rate

Secondary outcome measures
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 or toxicity.

Overall study start date
23/01/2006

Completion date
01/04/2007

Eligibility

Key inclusion criteria
1. Patients >/= 60 years
2. Patients considered unfit for standard chemotherapy
3. Patients with a confirmed diagnosis of
a. Acute myeloid leukemia (M0-M2 and M4-M7, FAB classification)

b. With refractory anemia with excess of blasts (RAEB) or refractory anemia with excess of blasts in transformation (RAEB-T) with an International Prognostic Scoring System (IPSS) score >/= 1.5
4. Subjects with secondary AML progressing from antecedent (at least 4 months duration) myelodysplasia are also eligible
5. Serum glutamic-oxaloacetic transaminase (SGOT)/aspartate aminotransferase (AST) or serum glutamic pyruvic transaminase (SGPT)/alanine aminotransferase (ALT), total serum bilirubin, serum creatinine, and creatinine clearance not more than 1.5 x the upper limit of normal (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 three months following the discontinuation of study drug
7. Written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
60

Key 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 six months prior to study entry
b. Reduced left ventricular ejection fraction of <50% as evaluated by echocardiogram or multiple-gated acquisition left ventricular (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

Date of first enrolment
23/01/2006

Date of final enrolment
01/04/2007

Locations

Countries of recruitment

Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3008 AE

Sponsor information

Organisation
Dutch Haemato-oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON)

Sponsor details
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Sponsor type
Research organisation

ROR
https://ror.org/056kpdx27

Funder(s)

Funder type
Research organisation

Funder Name
Dutch Cancer Society

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration