Randomized maintenance therapy with Azacitidine (Vidaza) in older patients (>= 60 years of age) with acute myeloid leukemia (AML) and refractory anemia with excess of blasts (RAEB, RAEB-t).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20498

Source
NTR

Brief title
HOVON 97 AML

Health condition

AML except FAB M3 or t(15;17), and RAEB or RAEB-t with IPSS >= 1.5, age >= 60 yrs.

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
Erasmus MC - Daniel den Hoed
Postbus 5201
3008 AE Rotterdam
Tel: 010 7041560
Fax: 010 7041028
e-mail: hdc@erasmusmc.nl
Source(s) of monetary or material Support: HOVON receives unrestricted financial

support from Celgene. In addition HOVON is supported by the Dutch Cancer Society.

Intervention

Outcome measures

Primary outcome

Disease-free survival measured from the date of randomization to relapse or death from any cause whichever comes first.

Secondary outcome

1. Overall survival measured from the date of randomization;

2. Probability of relapse and death after inclusion from date of randomization calculated as competing risks;

3. Number and duration of hospitalization as well as transfusion requirements (red cell and platelet transfusion);

4. Adverse events.

Study description

Background summary

Study phase: Phase 3.
Study objective: Evaluation of the effect of maintenance treatment with Azacitidine (Vidaza) for patients with <5% bone marrow blasts after 2 cycles of chemotherapy.
Patient population: Patients with AML except FAB M3 or t(15;17), and RAEB or RAEB-t with IPSS >= 1.5, age >= 60 yrs.
Study design: Prospective, multicenter, randomized phase III trial. Patients with <5% bone marrow blasts after 2 cycles of chemotherapy and who are not eligible for allogeneic hematopoietic cell transplantation, will be randomized for maintenance treatment or observation.
Duration of treatment: Patients randomized to Azacitidine (Vidaza), will receive maintenance treatment until relapse, for a maximum of 12 cycles. All patients will be followed for a maximum of 10 years after randomization.

Study objective

The hypothesis to be tested is that the outcome in arm B is better than in arm A.

Study design

At entry, during treatment every 4 weeks (or before start next cycle), in follow up every 4 weeks until relapse and thereafter every 4-8 weeks.

Intervention

Patients will be randomized between either maintenance therapy with Azacitidine or observation. Patients will receive maintenance treatment until relapse, for a maximum of 12 cycles.

Contacts

Public
Postbus 30001
G. Huls
UMCG, Department of Hematology
Groningen 9700 RB
The Netherlands
+31 (0)50 3612354
Scientific
Postbus 30001
G. Huls
UMCG, Department of Hematology
Groningen 9700 RB
The Netherlands
+31 (0)50 3612354

Eligibility criteria

Inclusion criteria

1. Age 60 years or more;

2. Subjects with a cytopathologically confirmed diagnosis of:

A. AML (M0-M2 and M4-M7, FAB classification);

B. Refractory anemia with excess of blasts (RAEB) or refractory anemia with excess of blasts in transformation (RAEB-t) with an IPSS score of >=1.5.

3. Less than 5% bone marrow blasts and absence of Auer rods after 2 cycles of induction therapy (this induction therapy can be according to HOVON81, HOVON92 or similar protocols);

4. Hematological recovery, i.e. ANC >= 0.5 x 109/l and platelets >= 50 x 109/l;

5. WHO performance status <= 2;

6. Written informed consent.

Exclusion criteria

1. Extramedullary disease;

2. Planned allogeneic hematopoietic cell transplantation;

3. Previous polycythaemia rubra vera;

4. Primary myelofibrosis;

5. Blast crisis of chronic myeloid leukemia;

6. AML-FAB type M3 or AML with cytogenetic abnormality t(15;17);

7. Impaired hepatic or renal function as defined by:

A. ALT and/or AST > 2.5 x normal value;

B. Bilirubin > 2 x normal value;

C. Serum creatinin > 2 x normal value (after adequate hydration).

8. Concurrent severe and/or uncontrolled medical condition (e.g. uncontrolled diabetes, infection, hypertension, cancer, etc.);

9. Cardiac dysfunction as defined by:

A. Myocardial infarction within the last 6 months of study entry;

B. Reduced left ventricular function with an ejection fraction <50% as measured by MUGA scan or echocardiogram;

C. Unstable angina.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2009
Enrollment:	126
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-05-2009
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	NL1700
NTR-old	NTR1810
Other	: 2008-001290-15
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A