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.

Gepubliceerd: 01-05-2006 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25417

Bron
NTR

Verkorte titel
HOVON / SAKK AML - 67

Aandoening

AML

Ondersteuning

Primaire 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 4391568
Fax: 010 4391028
e-mail: hdc@erasmusmc.nl
Overige ondersteuning: HOVON is supported by the Dutch Cancer Society.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

CR rate.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.)

Contactpersonen

Publiek

Erasmus Medical Center, Daniel den Hoed Cancer Center, Department of Hematology,
P.O. Box 5201
B. Löwenberg
Rotterdam 3008 AE

The Netherlands
+31 (0)10 4391598

Wetenschappelijk

Erasmus Medical Center, Daniel den Hoed Cancer Center, Department of Hematology,
P.O. Box 5201
B. Löwenberg
Rotterdam 3008 AE
The Netherlands
+31 (0)10 4391598

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	23-01-2006

Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	01-05-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A