A Phase II multicenter study to assess the tolerability and efficacy of the addition of Bevacizumab to standard induction therapy in AML and high risk MDS above 60 years.

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

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

Samenvatting

ID

NL-OMON20893

Bron
NTR

Verkorte titel
HOVON 81 AML

Aandoening

Acute Myeloid leukemia (AML), RAEB(-t)

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence of DLT and the effect of bevacizumab on the CR-rate

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase: Phase II
Study objective: Evaluation of the safety and tolerability of Bevacizumab added to standard induction chemotherapy. Evaluation of the effect of Bevacizumab on the CR rate
Patient population: Patients with AML (except FAB M3), RAEB or RAEB-t with IPSS ¡Ý 1.5, previously untreated, age > 60 yrs.
Study design: Prospective, multicenter, open-label, with randomization between standard induction chemotherapy with or without Bevacizumab.The initial Bevacizumab dose is 5 mg/kg i.v. on day 1+15 of each cycle. Decisions regarding dose escalation to 10 mg/kg, continuation with dose level 5 mg/kg, or stopping, are based on the incidence of DLT (dose limiting toxicity: death within 30 days of start cycle I and before start cycle II)Duration of treatment: Expected duration of 2 cycles of induction chemotherapy with of without Bevacizumab including evaluation is about 3 months.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

Patients will be randomized on entry between:
Arm A: Cycle I: daunorubicine/cytarabine-arabinoside. Cycle II: intermediate dose cytarabine-arabinoside.
Or Arm B: Cycle I: daunorubicine/cytarabine-arabinoside and 2 doses of bevacizumab 5 or 10 mg/kg. Cycle II: intermediate dose cytarabine-arabinoside and 2 doses of bevacizumab 5 or 10 mg/kg

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients > 60 years.
2. Patients eligible for standard chemotherapy.
3. Patients with a confirmed diagnosis of AML FAB M0-M2 or M4-M7 or 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. SGOT (AST) and SGPT (ALT) <= 1.5 x the upper limit of the normal range (ULN) at the laboratory where the analyses were performed.
6. Total serum bilirubin level <= 1.5 x the ULN at the laboratory where the analysis was performed.
7. Serum creatinine concentration <= 1.5 x the ULN at the laboratory where the analysis was performed.
8. Proteinuria at baseline: Urine dipstick of proteinuria <2+. Patients discovered to have >= 2+ proteinuria on dipstick urinalysis at baseline, should undergo a 24-hour urine collection and must demonstrate <= 1 g of protein/24 hr.
9. WHO performance status <= 2

10. 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. Past or current history (within the last 2 years prior to randomization) of malignancies except for the indication under this study and curatively treated basal and squamous cell carcinoma of the skin or in situ carcinoma of the cervix
3. Clinically significant (i.e. active) cardiovascular disease, for example cerebrovascular accidents (<= 6 months prior to randomization), myocardial infarction (<= 6 months prior to randomization), unstable angina, New York Heart Association (NYHA) grade II or greater congestive heart failure, serious cardiac arrhythmia requiring medication, reduced left ventricular ejection fraction of < 50% as evaluated by echocardiogram or MUGA scan.
4. Uncontrolled hypertension
5. Patients with a history of non-compliance to medical regimens or who are considered unreliable with respect to compliance
6. Patients with any serious concomitant medical condition which could, in the opinion of the investigator, compromise participation in the study.
7. Patients who have senile dementia, mental impairment or any other psychiatric disorder that prohibits the patient from understanding and giving informed consent.
8. Major surgical procedure, open biopsy, or significant traumatic injury within 28 days prior to study treatment start, or anticipation of the need for major surgical procedure during the course of the study
9. Serious, non-healing wound, ulcer, or bone fracture
10. Patients with bleeding diathesis or coagulopathy (unless related to AML)
11. Patients with known allergy to Chinese hamster ovary cell proteins or other recombinant human or humanized antibodies or to any excipients of bevacizumab formulation; or to any other study drugs.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-02-2007
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-02-2007
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	NL888
NTR-old	NTR904
Ander register	: HO81
ISRCTN	ISRCTN18332222

Resultaten

Samenvatting resultaten

N/A