An open label randomized controlled study in elderly subjects with previously untreated acute myelogenous leukaemia, comparing treatment groups randomised to receive daunorubicin and cytarabine or daunorubicin, cytarabine and PSC-833.

Gepubliceerd: 12-09-2005 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON25298

Bron
NTR

Verkorte titel
HOVON 31 AML / Novartis PSC C 302-E-00

Aandoening

AML

Ondersteuning

Primaire sponsor: Novartis Pharma AG
CH-4002 Basel
Switzerland
Overige ondersteuning: This study was supported by Novartis Pharmaceuticals. Data acquisition and the final analysis were independently performed at the HOVON Data Center.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Event-free survival.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase:

phase III.

Study objective:

evaluation of the effect of PSC-833 during induction treatment with daunorubicin and cytarabine;

Patient population:

patients with untreated AML, age >= 60 years.

Study design:

prospective, multicenter, randomized.

Duration of treatment:

duration of induction and consolidation treatment is maximum 5 months.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients with AML, meeting all eligibility criteria will be randomized on entry between:

Arm A: 2 induction cycles of daunorubicin (DNR) 45 mg/m^2/day, days 1-3 and cytarabine (Ara-C) 200 mg/m^2/day, days 1-7;

or

Arm B: 2 induction cycles of DNR 35 mg/m^2/day, days 1-3; Ara-C 200 mg/m^2/day, days 1-7; and PSC-833 loading dose 2 mg/kg over 2 hours, followed by 10 mg/kg/day, days 1-3;

Patients in CR will then be given one consolidation cycle without PSC-833 consisting of Ara-C, mitoxantrone and etoposide.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age >= 60 years;

2. Subjects who have a cytopathologically confirmed diagnosis of previously untreated AML (M0-M2 and M4-M7, FAB classification);

3. Subjects with secondary AML progressing from antecedent MDS are eligible if there has been no previous chemotherapy. Antecedent MDS is defined as any antecedent haematological disease of at least 4 months duration;

4. WHO performance status <= 2;

5. Subjects have given written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cytopathologically confirmed CNS infiltration. NB: in the absence of clinical suspicion of CNS involvement, lumbar puncture is not required;

2. Subjects have had previous Polycythemia Rubra Vera, primary myelofibrosis, are in blast cell crisis of chronic myeloid leukaemia or are M3 AML according to FAB classification;

3. Subject has neurosensory toxicity >= Grade 2 (NCIC Expanded CTC);

4. Subject has neurocerebellar toxicity >= Grade 1 (NCIC Expanded CTC);

5. Subject is known to be positive for human immunodeficiency virus (HIV) type 1 antibody (testing to determine HIV antibody status is not necessary to be eligible);

6. Subject has impairment of hepatic or renal function as defined by the following baseline laboratory values:

ALT and/or AST >= 2.5 times IULN

Alkaline phosphatase >= 2.5 times IULN

Serum total bilirubin >= 1.5 times IULN

Serum creatinine >= 1.5 times IULN after adequate hydration;

7. Subject is currently receiving treatment with any of the agents listed in Appendix 11 if treatment cannot be discontinued at the specified time relative to PSC-833 administration. All of the drugs listed are well substantiated to interact with cyclosporin A;

8. Subject has had major surgery within 2 weeks of study entry;

9. Subject has received investigational therapy within 30 days of study entry;

10. Subject has known hypersensitivity to cyclosporin A;

11. Subject has received prior radiotherapy within 4 weeks of study entry;

12. Subject is < 5 years free of another primary malignancy with the exception of basal cell carcinoma of the skin and stage 1 cervical carcinoma;

13. Subject has previously been treated with chemotherapy for AML;

14. Subject has concurrent severe and/or uncontrolled medical condition (e.g. uncontrolled diabetes, infection, hypertension etc.);

15. Subject has a psychological, intellectual or sensory dysfunction which is likely to impede their ability to understand and comply with study requirements;

16. Subject had a myocardial infarction within the last 6 months, has symptomatic ischaemic heart disease, congestive heart failure or other uncontrolled coronary disease.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-05-1997
Aantal proefpersonen:	400
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
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	NL322

Register	ID
NTR-old	NTR360
Ander register	: HO31
ISRCTN	ISRCTN11571826

Resultaten

Samenvatting resultaten

B. van der Holt, B. Löwenberg, A.K. Burnett, W.U. Knauf, J. Shepherd, P.P. Piccaluga, G.J. Ossenkoppele, G.E.G. Verhoef, A. Ferrant, M. Crump, D. Selleslag, M. Theobald, M.F. Fey, E. Vellenga, M. Dugan and P. Sonneveld. The value of the MDR1 reversal agent PSC-833 in addition to daunorubicin and cytarabine in the treatment of elderly patients with previously untreated acute myeloid leukemia (AML), in relation to MDR1 status at diagnosis. Blood, in press. 2005