A randomized phase III study in previously untreated patients with biological high-risk CLL: Fludarabine + cyclophosphamide (FC) versus FC + low-dose alemtuzumab.

No registrations found.

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

Summary

ID

NL-OMON25345

Source
NTR

Brief title
HOVON 68 CLL

Health condition

Chronic Lymphocytic Leukemia

Sponsors and support

Primary sponsor: Dr. C.H. Geisler
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HOVON receives unrestricted grants and/or financial support from Amgen, Johnson&Johnson-Orthobiotech, Roche and Novartis for the execution of investigator sponsored trials. In addition HOVON is supported by the Dutch Cancer Society.

Intervention

Outcome measures

Primary outcome

Progression free survival (i.e. time from registration to disease progression, relapse or death due to CLL whichever occurs first).

Secondary outcome

1. Event free survival (i.e. time from registration to induction failure, progression, relapse or death whichever occurs first); the time to failure of patients with induction failure is set at one day;

2. Clinical, flow cytometric and molecular response rate;

3. Overall survival;

4. Disease free survival (i.e. time from CR to relapse);

5. Toxicity.

Study description

Background summary

Study phase: Phase III

Study objectives: Determination of the efficacy and safety of oral fludarabine and cyclophosphamide plus concomitant s.c. alemtuzumab compared to fludarabine and cyclophosphamide alone in terms of progression free survival, event free survival, clinical, flow cytometric and molecular response rates, overall survival and disease free survival.

Patient population: Patients with biological high-risk CLL in symptomatic stage A or B or stage C, irrespective of duration of disease, age 18-75 years inclusive.

Study design: Prospective, multicenter, randomized

Duration of treatment: Expected duration of treatment is 24 weeks.

Study objective

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

Intervention

All eligible patients will be randomized on entry between:

1. Arm A: 6 cycles of oral FC;

2. Arm B: 6 cycles of oral FC combined with s.c. alemtuzumab.

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Eligibility criteria

Inclusion criteria

1. Biological high-risk CLL;

2. Patients with symptomatic stage A, symptomatic stage B or stage C;

3. Age 18-75 years inclusive;

4. Written informed consent.

Exclusion criteria

1. WHO performance status >= 3, unless related to CLL;

2. Intolerance of exogenous protein administration;

3. Severe cardiac dysfunction (NYHA classification III-IV);

4. Significant renal dysfunction (serum creatinine >= 150 micromol/l or creatinine clearance < 30 ml/min);

5. Significant hepatic dysfunction (total bilirubin or transaminases > 2 times ULN), unless related to CLL;

6. Suspected or documented CNS involvement by CLL;

7. Known HIV positivity;

8. Active, uncontrolled infections;

9. Uncontrolled asthma or allergy requiring systemic steroid treatment;

10. Previously treated with chemotherapy, radiotherapy or immunotherapy for CLL;

11. History of active cancer during the past 5 years, except non-melanoma skin cancer or stage 0 cervical carcinoma;

12. Clinically significant auto-immune hemolytic anemia (AIHA);

13. Female patients who are pregnant or nursing;

14. Male and female patients of reproductive potential who are not practicing effective means of contraception, these include oral contraceptives, intrauterine device, depot injection of gestagen, subdermal implantation, hormonal vaginal ring and transdermal depot plaster.
These methods must be applied for the entire protocol treatment period, and for patients treated with alemtuzumab until at least 6 months after the end of alemtuzumab

administration.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-12-2005
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-11-2005
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	NL487
NTR-old	NTR529
Other	: HO68
ISRCTN	ISRCTN25180151

Study results

Summary results
N/A