ISRCTN25180151 https://doi.org/10.1186/ISRCTN25180151

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

Submission date
14/02/2006

Registration date
14/02/2006

Last Edited
14/02/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HO68

Study information

Scientific Title

Acronym
HOVON 68 CLL

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective, multicenter, randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic Lymphocytic Leukemia (CLL)

Interventions
All eligible patients will be randomized on entry between:
Arm A: 6 cycles of oral FC
Arm B: 6 cycles of oral FC combined with sc alemtuzumab

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Fludarabine and cyclophosphamide (FC) and low-dose alemtuzumab

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

Key secondary outcome(s))
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

Completion date
31/12/2008

Eligibility

Key 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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. WHO performance status >/= 3, unless related to CLL
2. Intolerance of exogenous protein administration
3. Severe cardiac dysfunction (New York Heart Association [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 upper limit of normal [ULN]), unless related to CLL
6. Suspected or documented central nervous system (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.

Date of first enrolment
05/12/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Rigshospitalet (Denmark)

ROR
https://ror.org/03mchdq19

Funder(s)

Funder type
Industry

Funder Name
Dutch Cancer Society and Schering AG (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration