

Fludarabine versus Fludarabine plus Cyclophosphamide in first line therapy of younger patients (up to 65 years) with advanced Chronic Lymphocytic Leukemia

Submission date 02/03/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/04/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/01/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00276848

Protocol serial number
CLL4

Study information

Scientific Title

Fludarabine plus cyclophosphamide versus fludarabine alone in first-line therapy of younger patients with chronic lymphocytic leukemia

Acronym

F versus FC in CLL

Study objectives

If the combination therapy fludarabine plus cyclophosphamide, which has been shown very promising results in phase II studies, is superior to the chemotherapy with fludarabine alone, which is so far the standard first line treatment in Chronic Lymphocytic Leukemia (CLL) patients with physical good condition.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Chronic lymphocytic leukemia (CLL),
advanced stage

Interventions

Fludarabine 25 mg/m²/day intravenously for five days, repeated every 28 days, maximum of six courses.

Fludarabine 30 mg/m²/day for three days intravenously plus cyclophosphamide 250 mg/m²/day for three days, both repeated every 28 days, maximum of six courses.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Fludarabine, cyclophosphamide

Primary outcome(s)

Response rates, quality of responses as well as progression free survival.

Key secondary outcome(s)

Survival, as well as toxicity and quality of life.

Completion date

31/07/2003

Eligibility

Key inclusion criteria

Patients with an age of up to 65 years with untreated CLL in advanced stage (all Binet stage C patients; Binet stage B with symptoms, which require therapy; Binet stage A with severe B-symptoms).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Patients with an age less than 18 and more than 65 years were excluded as well as patients with any previous treatment of CLL, life expectancy less than six months and an Eastern Cooperative Oncology Group performance status of more than two. Patients were also excluded if they had severe organ dysfunction, concomitant or previous other neoplasms or an autoimmune hemolytic anemia or thrombocytopenia.

Date of first enrolment

01/07/1999

Date of final enrolment

31/07/2003

Locations

Countries of recruitment

Austria

Germany

Study participating centre

Kerpernerstr. 62

Cologne

Germany
50937

Sponsor information

Organisation
German CLL Study Group (GCLLSG)

Funder(s)

Funder type
Research organisation

Funder Name
CLL4 trial of the Geman CLL Study Group (GCLLSG)

Funder Name
MedacSchering Onkologie

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2006	25/01/2019	Yes	No
Results article	results	01/05/2007	25/01/2019	Yes	No