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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

Registration date
26/04/2005

Last Edited
25/01/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00276848

Secondary identifying numbers
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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Chronic lymphocytic leukemia (CLL),
advanced stage

Interventions
Fludarabine 25 mg/m^2/day intravenously for five days, repeated every 28 days, maximum of six courses.
Fludarabine 30 mg/m^2/day for three days intravenously plus cyclophosphamide 250 mg/m^2 /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 measure
Repsonse rates, quality of responses as well as progression free survival.

Secondary outcome measures
Survival, as well as toxicity and quality of life.

Overall study start date
01/07/1999

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
375

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)

Sponsor details
Department of Internal Medicine I
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50924
-
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Sponsor type
Not defined

Funder(s)

Funder type
Research organisation

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

Funder Name
MedacSchering Onkologie

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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