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Treatment of advanced, relapsed chronic lymphocytic leukemia (CLL) with fludarabine, miroxantrone and cyclophosphamide combination therapy with or without granulocyte colony stimulating factor (G-CSF)

Submission date 30/06/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/10/2005	**Overall study status** Completed	
Last Edited 09/11/2009	**Condition category** Cancer	

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

Secondary identifying numbers
CLL6 protocol

Study information

Scientific Title

Study objectives
The prophylactic administration of G-CSF prevents the incidence of infections during relapse chemotherapy in chronic lymphocytic leukemia (CLL) patients

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Relapsed B-cell chronic lymphocytic leukemia (B-CLL)

Interventions
Fludarabine 25 mg/m^2 day 1-3, mitoxantrone 8 mg/m^2 day 1, cyclophosphamide 200 mg/m^2 day 1-3, repeated every 28 days, maximum 6 courses.

Arm A with G-CSF: 5 µg/kg bodyweight/day subcutaneously (sc) beginning on day +6 until neutrophil recovery above 1500/µl.
Arm B without G-CSF.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Fludarabine, miroxantrone, cyclophosphamide and G-CSF

Primary outcome measure
1. Incidence of severe and life threatening infections
2. Incidence of severe side effects
3. Remission rate

Secondary outcome measures
1. Overall survival
2. Progression free survival
3. Quality of remission

Overall study start date
06/08/1999

Completion date
30/09/2004

Eligibility

Key inclusion criteria
1. B-cell chronic lymphocytic leukemia (B-CLL)
2. Binet stage C, Binet stage B with treatment indication
3. Maximum of 3 previous treatment regimen
4. Age 18-70 years
5. Life expectancy more than 6 months
6. Eastern Cooperative Oncology Group (ECOG) 0-3
7. Normal cardiac function
8. Signed inform consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
165

Key exclusion criteria
1. Severe organ dysfunction
2. Autoimmune haemolytic anaemia (AIHA)
3. More than 3 chemotherapy regimens
4. Concomitant or previous neoplasm
5. Non-response to previous treatment with Fludarabine + Cyclophosphamide, Fludarabine + Mitoxantrone, Fludarabine + Epirubicine

Date of first enrolment
06/08/1999

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
Germany

Study participating centre
Kerpenerstr. 62
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Sponsor information

Organisation
German CLL Study Group (GCLLSG) (Germany)

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Herderstr. 52-54
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Sponsor type
Research organisation

Website
http://www.dcllsg.de

Funder(s)

Funder type
Industry

Funder Name
Amgen (USA)

Alternative Name(s)
Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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