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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
Registration date 11/10/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/11/2009	**Condition category** Cancer	[_] 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
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

Study type(s)
Treatment

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(s)
1. Incidence of severe and life threatening infections
2. Incidence of severe side effects
3. Remission rate

Key secondary outcome(s))

1. Overall survival
2. Progression free survival
3. Quality of remission

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

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
Cologne
Germany
50924

Sponsor information

Organisation
German CLL Study Group (GCLLSG) (Germany)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration