

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

Contact name
Prof Michael Hallek

Contact details
Kerpenerstr. 62
Cologne
Germany
50924
+49 221 478 4400
michael.hallek@uk-koeln.de

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Relapsed B-cell chronic lymphocytic leukemia (B-CLL)

Interventions

Fludarabine 25 mg/m² day 1-3, mitoxantrone 8 mg/m² day 1, cyclophosphamide 200 mg/m² 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, mitoxantrone, 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