

Treatment of elderly patients with advanced chronic lymphocytic leukemia (CLL) with fludarabine versus chlorambucil

Submission date 30/06/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/09/2009	Condition category Cancer	<input type="checkbox"/> 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)
NCT00262795

Protocol serial number
CLL5 protocol

Study information

Scientific Title

Study objectives

Superiority of fludarabine compared to chlorambucil in elderly 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

B-Chronic Lymphocytic Leukemia (CLL)

Interventions

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

Chlorambucil 0.4 mg/kg bodyweight with increasing of the dose up to 0.8 mg/kg bodyweight, q 15 days, maximum 12 months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Fludarabine and chlorambucil

Primary outcome(s)

Progression free survival, overall survival, duration of remission, quality of remission.

Key secondary outcome(s))

1. Toxicity
2. Quality of life

Completion date

30/09/2004

Eligibility

Key inclusion criteria

1. B-CLL
2. Binet stage C or Binet stage B with symptoms, which require therapy, or Binet stage A with severe B-symptoms
3. Age 66 - 79 years
4. No previous treatment
5. Signed informed-consent
6. Life expectancy of more than six months
7. Eastern Cooperative Oncology Group (ECOG) status zero, one or two

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Severe organ dysfunction
2. Concomitant or previous neoplasm

Date of first enrolment

01/07/1999

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)

Funder(s)

Funder type

Industry

Funder Name

German Cancer Aid (Deutsche Krebshilfe) (Germany)

Funder Name

Medac Schering Onkologie GmbH (Germany)

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	15/10/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes