

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

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

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.dcllsg.de/en/cll5/index.php>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00262795

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

B-Chronic Lymphocytic Leukemia (CLL)

## Interventions

Fludarabine 25 mg/m<sup>2</sup> 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 measure**

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

**Secondary outcome measures**

1. Toxicity
2. Quality of life

**Overall study start date**

01/07/1999

**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

**Age group**

Senior

**Sex**

Both

**Target number of participants**

200

**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

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**Sponsor information****Organisation**

German CLL Study Group (GCLLSG)

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.dcllsg.de>

**Funder(s)****Funder type**

Industry

**Funder Name**

German Cancer Aid (Deutsche Krebshilfe) (Germany)

**Funder Name**

Medac Schering Onkologie GmbH (Germany)

# 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?
<a href="#">Results article</a>	results	15/10/2009		Yes	No