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

Submission date	Recruitment status	[_] Prospectively registered
30/06/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/09/2009	Cancer	

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

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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^2 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
Herderstr. 52-54
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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?
Results article	results	15/10/2009		Yes	No