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Prognostic factors and early risk-adapted therapy in patients with chronic lymphocytic leukemia in Binet stage A

Submission date 31/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/10/2005	**Overall study status** Completed	
Last Edited 12/02/2020	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CLL1

Study information

Scientific Title
-

Study objectives
1. Identification of a group of high risk patients in Binet stage A
2. Evaluation of the efficacy of an early risk-adapted therapy in Binet stage A 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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic Lymphocytic Leukemia (CLL) Binet stage A, untreated

Interventions
1. Intervention: randomised treatment with fludarabine (25 mg/m^2, days one to five, every 28 days, for a maximum of six courses) in high risk patients
2. Control: Watch and wait

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fludarabine

Primary outcome measure
Progression-free survival

Secondary outcome measures
1. Overall survival
2. Quality of life
3. Incidence of infections

Overall study start date
01/07/1997

Completion date
30/09/2004

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of Chronic Lymphocytic Leukemia (CLL) in Binet stage A
2. Initial diagnosis within the last three years
3. No previous therapy
4. Age between 18 and 75 years
5. Eastern Cooperative Oncology Group (ECOG) status zero to two
6. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
320

Total final enrolment
539

Key exclusion criteria
1. Autoimmune cytopenia
2. Severe concommitant disease
3. Concomitant secondary neoplasia
4. Participation in another clinical trial

Date of first enrolment
01/07/1997

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)

Sponsor details
Department of Internal Medicine I
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Sponsor type
Research organisation

Website
http://www.dcllsg.de

Funder(s)

Funder type
Charity

Funder Name
German Cancer Aid (Deutsche Krebshilfe), Bonn (Germany)

Funder Name
German Chronic Lymphocytic Leukemia Study Group (GCLLSG), Cologne (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	01/04/2020	12/02/2020	Yes	No