

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
Registration date 06/10/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/02/2020	Condition category Cancer	☐ 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

Protocol serial number
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic Lymphocytic Leukemia (CLL) Binet stage A, untreated

Interventions

1. Intervention: randomised treatment with fludarabine (25 mg/m², 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(s)

Progression-free survival

Key secondary outcome(s))

1. Overall survival
2. Quality of life
3. Incidence of infections

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

539

Key exclusion criteria

1. Autoimmune cytopenia
2. Severe concomitant 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)

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

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