

Phase III, open-label, randomised, multicentre efficacy and safety study of bendamustine hydrochloride versus chlorambucil in treatment-naive patients with (Binet Stage B/C) chronic B-Cell Lymphocytic Leukaemia (B-CLL) requiring therapy

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
20/10/2005	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
23/11/2005	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
10/06/2021	Cancer	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

Study information

Scientific Title

Phase III, open-label, randomised, multicentre efficacy and safety study of bendamustine hydrochloride versus chlorambucil in treatment-naive patients with (Binet Stage B/C) chronic B-Cell Lymphocytic Leukaemia (B-CLL) requiring therapy

Study objectives

The proof of efficacy and tolerability of bendamustine in comparison to chlorambucil in the first line treatment of B-Cell Lymphocytic Leukaemia (B-CLL).

Please note that as of 29/10/2007 the funder and sponsor of this record were changed. The previous funder and sponsor was Ribosepharm GmbH (Germany). This change was made due to a change in the licensee of bendamustine: Ribosepharm GmbH was the licensee until April 31, 2007. After this date Mundipharma Research Ltd became the new licensee and took over the responsibility for the ongoing clinical trials with bendamustine.

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-Cell Lymphocytic Leukaemia (B-CLL)

Interventions

Arm A: Bendamustine 100 mg/m² days 1 + 2 repeated every 28 days

Arm B: Chlorambucil 0.8 mg/kg (Broca's normal weight) day 1 + day 15 every 28 days

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Bendamustine hydrochloride, chlorambucil

Primary outcome(s)

1. Overall response rate
2. Progression-free survival

Key secondary outcome(s)

1. Time to progression
2. Duration of response
3. Overall survival
4. Infection rate
5. Quality of life
6. Toxicity

Completion date

01/06/2007

Eligibility

Key inclusion criteria

1. Treatment-naive
2. Confirmed chronic B-cell lymphocytic leukemia
3. Symptomatic Binet stage B or Binet stage C disease
4. Written informed consent
5. World Health Organization (WHO) performance status 0 - 2
6. Life expectancy greater than 3 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

319

Key exclusion criteria

1. Previous treatment with other cytotoxic drugs
2. Participation in another clinical trial within 4 weeks prior to or during this study
3. Mental disorders
4. History of a second malignancy
5. Manifest immune hemolysis or immune thrombocytopenia that can be treated with glucocorticoids alone
6. Richter's syndrome or transformation to Prolymphocytic Leukemia (PLL)
7. Abnormal liver, renal and cardiac function
8. Known Human Immunodeficiency Virus (HIV) infection

9. Major surgery within 30 days before the start of the trial

10. Pregnancy

11. Lactation

Date of first enrolment

01/11/2002

Date of final enrolment

01/06/2007

Locations

Countries of recruitment

Germany

Study participating centre

Gemeinschaftspraxis Oncology & Hematology

Frankfurt

Germany

60389

Sponsor information

Organisation

Mundipharma Research Ltd (UK)

ROR

<https://ror.org/025194b42>

Funder(s)

Funder type

Industry

Funder Name

Mundipharma Research Ltd (UK)

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		10/09/2009	10/06/2021	Yes	No