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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
20/10/2005

Recruitment status
No longer recruiting

Registration date
23/11/2005

Overall study status
Completed

Last Edited
10/06/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
02CLLIII

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

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
B-Cell Lymphocytic Leukaemia (B-CLL)

Interventions
Arm A: Bendamustine 100 mg/m^2 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 measure
1. Overall response rate
2. Progression-free survival

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

Overall study start date
01/11/2002

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

Age group
Adult

Sex
Both

Target number of participants
350

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
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Sponsor information

Organisation
Mundipharma Research Ltd (UK)

Sponsor details
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Sponsor type
Industry

ROR
https://ror.org/025194b42

Funder(s)

Funder type
Industry

Funder Name
Mundipharma Research Ltd (UK)

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