

Phase III trial of combined immunochemotherapy with Fludarabine, Cyclophosphamide and Rituximab (FC-R) versus chemotherapy with Fludarabine and Cyclophosphamide (FC) alone in patients with previously untreated chronic lymphocytic leukaemia

Submission date 21/11/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/12/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/09/2021	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

CLL-8

Study information

Scientific Title

Phase III trial of combined immunochemotherapy with Fludarabine, Cyclophosphamide and Rituximab (FC-R) versus chemotherapy with Fludarabine and Cyclophosphamide (FC) alone in patients with previously untreated chronic lymphocytic leukaemia

Acronym

CLL-8

Study objectives

The objective of this study is to determine the value of immunochemotherapy with FCR in comparison with chemotherapy with FC alone in the first-line therapy of B-CLL. The study is to answer the following questions:

1. Is combined immunochemotherapy with FCR superior to chemotherapy with FC alone in the first-line therapy of B-CLL?
2. Is combined immunochemotherapy with FCR a safe alternative to FC chemotherapy alone with regards to the adverse effects

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic lymphocytic leukaemia (CLL)

Interventions

Patients will be randomised between combined immunochemotherapy with Fludarabine, Cyclophosphamide and Rituximab (FCR) (Arm A) versus chemotherapy with Fludarabine and Cyclophosphamide (FC) alone (Arm B).

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Fludarabine, Cyclophosphamide, Rituximab, Cyclophosphamide

Primary outcome(s)

Progression-free survival (PFS)

Key secondary outcome(s)

1. Event-free survival
2. Overall survival
3. Disease-free survival
4. Duration of remission
5. Time to new CLL treatment or death
6. Rates of molecular, complete and partial remission
7. Response rates and survival times in biological subgroups
8. Rates of treatment-related adverse effects
9. Pharmacoeconomic impact
10. Quality of life

Completion date

30/09/2008

Eligibility

Key inclusion criteria

1. Confirmed diagnosis of B-CLL according to National Cancer Institute (NCI)/German CLL Study Group (GCLLSG) criteria
2. Need for treatment
3. Age ≥ 18 years
4. Life expectancy > 6 months
5. Eastern Cooperative Oncology Group (ECOG) performance status 0-1
6. Patient's written informed consent
7. Willingness to contraception for the entire duration of the treatment and 2 months thereafter

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

552

Key exclusion criteria

1. Manifest autoimmune cytopaenias including Coombs-positive autoimmune haemolytic anaemia
2. Active second malignancy requiring treatment (except basal cell carcinoma or malignant tumour treated curatively by surgery)
3. Prior chemotherapy and/or radiotherapy
4. Pregnancy, nursing
5. Concomitant disease requiring prolonged use of glucocorticoids (>1 month)
6. Hypersensitivity with anaphylactic reaction to humanised monoclonal antibodies or any of the study drugs
7. Active bacterial, viral or fungal infection
8. Creatinine clearance <70 ml/min
9. Total bilirubin >2 fold of upper normal limit
10. Total cumulative illness rating scale (CIRS) score >6
11. Cerebral dysfunction, legal incapacity
12. Richter's syndrome

Date of first enrolment

01/07/2003

Date of final enrolment

30/09/2008

Locations**Countries of recruitment**

Germany

Study participating centre

Direktor der Klinik I für Innere Medizin

Koeln

Germany

D-50924

Sponsor information**Organisation**

German CLL Study Group - GCLLSG (Germany)

Funder(s)

Funder type

Industry

Funder Name

Hoffmann-La Roche AG (Protocol ML17102)

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		01/04/2010	23/09/2021	Yes	No