ISRCTN02757147 https://doi.org/10.1186/ISRCTN02757147

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/12/2003	**Overall study status** Completed	
Last Edited 23/09/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Michael Hallek

Contact details
Direktor der Klinik I für Innere Medizin
Universitaet zu Koeln
Joseph-Stelzmann-Str. 9
Koeln
Germany
D-50924
+49 (0)221 478 4400
michael.hallek@uni-koeln.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Progression-free survival (PFS)

Secondary outcome measures
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

Overall study start date
01/07/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
760

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)

Sponsor details
Department of Internal Medicine I
University of Cologne
Cologne
Germany
50924
+49 (0)221 478 3988
cllstudie@uk-koeln.de

Sponsor type
Research organisation

Funder(s)

Funder type
Industry

Funder Name
Hoffmann-La Roche AG (Protocol ML17102)

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