

A randomised comparison of chlorambucil, fludarabine and fludarabine plus cyclophosphamide

Submission date 01/07/2001	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/10/2018	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

ClinicalTrials.gov (NCT)
NCT00004218

Clinical Trials Information System (CTIS)
2004-000105-21

Protocol serial number

LRF CLL4

Study information

Scientific Title

Conventional therapy with chlorambucil versus fludarabine, used alone or in a novel combination with cyclophosphamide: a randomised controlled trial

Acronym

CLL 4

Study objectives

This study will compare conventional therapy with chlorambucil versus the new agent fludarabine, used alone or in a novel combination with cyclophosphamide. End points of the trial will be:

1. Survival
2. Response to therapy
3. Duration of response
4. Toxicity
5. Quality of life

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Thames MREC initially approved of this trial in 1998 (ref. no: MREC 98/1/101). An amendment to the protocol was accepted on 27th February 2001.

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 chlorambucil versus fludarabine based treatment. Half of the patients randomised to fludarabine will be randomised between fludarabine plus cyclophosphamide and fludarabine alone.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Chlorambucil, fludarabine, fludarabine, cyclophosphamide

Primary outcome(s)

Survival

Key secondary outcome(s)

1. Response to therapy
2. Duration of response
3. Toxicity
4. Quality of life

Completion date

30/10/2004

Eligibility

Key inclusion criteria

1. Patients are diagnosed with B-cell chronic lymphocytic leukaemia
2. They have not previously been treated
3. They have been diagnosed by a persistent lymphocytosis and bone marrow infiltration of at least 40% and require treatment
4. They are classified as having stage A progressive, stage B or stage C disease using the International Binet Staging System
5. They have given informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

1. Patients with other life-threatening diseases
2. Patients unable or unwilling to give informed consent
3. Renal failure (creatinine clearance less than 30 ml/min)
4. Hepatic enzymes and bilirubin greater than twice the upper limit of normal, unless due to CLL
5. Pregnant women or women at risk of pregnancy
6. Patients who for other reasons are not expected to complete the study
7. Patients with a diagnosis other than CLL after central review of markers and morphology

Date of first enrolment

01/02/1999

Date of final enrolment

30/10/2004

Locations

Countries of recruitment

United Kingdom

England

Argentina

Croatia

Greece

Ireland

Italy

New Zealand

Russian Federation

Study participating centre

Section of Haemato-Oncology

Sutton

United Kingdom

SM2 5NG

Sponsor information

Organisation

Institute of Cancer Research (UK)

ROR

<https://ror.org/043jzw605>

Funder(s)

Funder type

Charity

Funder Name

Leukaemia Research Fund (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	results of assessment of fludarabine plus cyclophosphamide for patients with chronic lymphocytic leukaemia	21/07/2007		Yes	No
Results article	results on the scan of nonsynonymous SNPs in CLL4 trial patients for the identification of genetic variants influencing prognosis	01/02/2008		Yes	No
Results article	results on the prognostic significance of a positive direct antiglobulin test in chronic lymphocytic leukemia	15/02/2008		Yes	No
Results article	results on baseline health-related quality of life	01/12/2008		Yes	No
Results article	results of identification of prognostic makers	01/10/2010		Yes	No
Results article	results of relative importance of prognostic makers	01/10/2010		Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes