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A randomised comparison of chlorambucil, fludarabine and fludarabine plus cyclophosphamide

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 17/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.icr.ac.uk/research/research_sections/haemato_oncology/4448.shtml

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2004-000105-21

IRAS number

ClinicalTrials.gov number
NCT00004218

Secondary identifying numbers
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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Survival

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

Overall study start date
01/02/1999

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

Age group
Not Specified

Sex

Both

Target number of participants
750 (initially 500)

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
Argentina

Croatia

England

Greece

Ireland

Italy

New Zealand

Russian Federation

United Kingdom

Study participating centre
Section of Haemato-Oncology
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Sponsor information

Organisation
Institute of Cancer Research (UK)

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Sponsor type
Research organisation

Website
http://www.icr.ac.uk/

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Leukaemia Research Fund (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?
Plain English results				No	Yes
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