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Third Medical Research Council Trial in Chronic Lymphomatic Leukaemia

Submission date	Recruitment status	[ ] Prospectively registered
19/08/2002	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/08/2002	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/10/2019	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof D Catovsky

Contact details
Royal Marsden Hospital
Fulham Road
London
United Kingdom
SW3 6JJ
+44 (0)20 7352 8171
abc@email.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G8223452

Study information

Scientific Title
Third Medical Research Council Trial in Chronic Lymphomatic Leukaemia

Acronym
MRC CLL3

Study objectives
To establish whether the addition of epirubicin to standard chlorambucil therapy prolongs the duration of remission and survival, to evaluate the therapeutic benefit of anthracyclines in CLL by comparing the objective response rate to chlorambucil alone with that to chlorambucil + epirubicin, to assess the relative toxicities of two regimens.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Leukaemia (chronic)

Interventions
Following randomisation stage C patients only receive pre-treatment with prednisolone. Patients are then treated on one of two treatment regimens depending upon the initial randomisation:
1. Regimen A: Chlorambucil orally daily for 6 days. Cycle repeated every 28 days.
2. Regimen B: Epirubicin on day 1 followed by chlorambucil orally for 6 days. Cycle to be repeated every 28 days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
anthracyclines

Primary outcome measure
Death and death related to CLL, response to treatment, toxicity and compliance

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/1990

Completion date
01/04/1995

Eligibility

Key inclusion criteria
1. All patients with B-cell chronic lymphoblastic leukaemia diagnosed by a persistent blood lymphocytosis (greater than 10 x 10^9/l) and bone marrow infiltration of at least 40% who require treatment
2. Previously untreated stage B and C disease
3. Stage A patients showing evidence of disease progression
4. Previously treated patients who:
4.1 Have not received an anthracycline or anthracenedione
4.2 Are not considered to be resistant to chlorambucil
4.3 Have relapsed off therapy and need further treatment because of disease progression
5. No concomitant treatment with any other cytotoxic or immunomodulatory therapy
6. No other life threatening disease
7. No medical contraindications to treatment protocols

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
350

Key exclusion criteria

Patients who have another life threatening disease; they are not expected to complete the study treatment for other reasons; they are having concomitant treatment with any cytotoxic or immunomodulatory therapy; there is evidence of heart disease which would preclude treatment with anthracycline or they have not given informed consent.

Date of first enrolment
01/04/1990

Date of final enrolment
01/04/1995

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Marsden Hospital
London
United Kingdom
SW3 6JJ

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

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

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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