

Third Medical Research Council Trial in Chronic Lymphomatic Leukaemia

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/10/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 $10 \times 10^9/l$) 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

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+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