# 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	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

Prof D Catovsky

#### Contact details

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# Additional identifiers

Protocol serial number G8223452

# Study information

#### Scientific Title

Third Medical Research Council Trial in Chronic Lymphomatic Leukaemia

#### Acronym

#### **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

#### Study type(s)

Treatment

#### 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(s)

Death and death related to CLL, response to treatment, toxicity and compliance

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

# **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

#### Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### 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

United Kingdom

England

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

# Sponsor information

#### Organisation

Medical Research Council (MRC) (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**

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?

Participant information sheet