

A randomised Phase II Trial of fludarabine, cyclophosphamide and mitoxantrone (FCM) with or without rituximab (R) in previously treated chronic lymphocytic leukaemia

Submission date 24/08/2004	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 21/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/10/2018	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-of-chemotherapy-with-or-without-rituximab-for-chronic-lymphocytic-leukaemia>

Contact information

Type(s)

Scientific

Contact name

Dr Peter Hillmen

Contact details

Department of Haematology
Brotherton Wing
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00337246

Clinical Trials Information System (CTIS)

2004-003982-34

Study information

Scientific Title

A randomised Phase II Trial of fludarabine, cyclophosphamide and mitoxantrone (FCM) with or without rituximab (R) in previously treated chronic lymphocytic leukaemia

Acronym

UKCLL 01 FCM/FCM-R

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomized, controlled, open-label, parallel group, multicenter study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic Lymphocytic Leukaemia (CLL)

Interventions

All patients will receive fludarabine with cyclophosphamide plus mitoxantrone (FCM) and half will be randomised to receive simultaneous rituximab (FCM-R)

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

cyclophosphamide, fludarabine phosphate, mitoxantrone, rituximab

Primary outcome(s)

Not provided at time of registration.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

31/07/2008

Eligibility

Key inclusion criteria

CLL requiring therapy, had previous treatment with at least one chemotherapeutic regimen, be capable of giving written informed consent, World Health Organisation (WHO) 0, 1 or 2, life expectancy of at least 12 weeks.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Previous treatment with F (or other purine analogues) combined with C and M, previous treatment with R, past history of anaphylaxis following exposure to rat or mouse derived complementarity determining region grafted humanized monoclonal antibodies, toxicity attributable to purine analogues, active infection, other severe, concurrent diseases or mental disorders that could interfere with their ability to participate in the study, patients with a creatinine clearance of less than 30 ml/min (measured or derived by the Cockcroft formula), pregnant or unwilling to use adequate contraception.

Date of first enrolment

01/07/2005

Date of final enrolment

31/07/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Haematology
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Leeds Acute NHS Trust (UK)

Funder(s)

Funder type
Industry

Funder Name
ML175555 Roche pharmaceutical have provided an educational grant covering the costs of the trial

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	01/03/2011		Yes	No
Plain English results				No	Yes