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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

Registration date
21/09/2004

Last Edited
19/10/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
2004-003982-34

ClinicalTrials.gov (NCT)
NCT00337246

Protocol serial number
N/A

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

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

Primary study design
Interventional

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes