Phase II randomised study of fludarabine /cyclophosphamide combination with or without rituximab in patients with untreated mantle cell lymphoma

Submission date	Recruitment status	Prospectively registered
12/09/2003 Registration date	No longer recruiting Overall study status	☐ Protocol
		Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
30/11/2015	Cancer	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number 2005-003178-71

IRAS number

ClinicalTrials.gov number

NCT00053092

Secondary identifying numbers

N0231120090

Study information

Scientific Title

The addition of Rituximab to Fludarabine and Cyclophosphamide chemotherapy results in a significant improvement in overall survival in patients with newly diagnosed mantle cell lymphoma

Study objectives

Drugs used in chemotherapy use different ways to stop cancer cells from dividing so they stop growing or die. Monoclonal antibodies such as rituximab can locate cancer cells and either kill them or deliver cancer-killing substances to them without harming normal cells. It is not yet known if combination chemotherapy is more effective with or without rituximab in treating mantle cell lymphoma.

This is a randomised phase II trial to compare the effectiveness of fludarabine and cyclophosphamide combined with rituximab to that of fludarabine and cyclophosphamide alone in treating patients who have mantle cell lymphoma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from Multicentre Research Ethics Committee (ref: 02/6/31)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cancer: untreated mantle cell lymphoma

Interventions

- 1. Fludarabine intravenous (IV) and cyclophosphamide IV on days 1 3
- 2. Rituximab IV on day 1 and fludarabine IV and cyclophosphamide IV on days 2 4

Treatment repeats every 28 days for 2 - 8 courses in the absence of disease progression or unacceptable toxicity.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Fludarabine/cyclophosphamide, rituximab

Primary outcome measure

- 1. Response rate
- 2. Time to disease progression
- 3. Toxicity
- 4. Overall survival

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/10/2002

Completion date

22/02/2005

Eligibility

Key inclusion criteria

- 1. Age 18 years or older
- 2. Proven mantle cell lymphoma
- 3. Previously untreated disease at any stage requiring therapy
- 4. No previous chemotherapy
- 5. Life expectancy of at least 3 months
- 6. Signed and dated informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

151

Key exclusion criteria

- 1. Known serological positivity for hepatitis B virus (HBV), hepatitis C virus (HCV) or human immunodeficiency virus (HIV)
- 2. Pregnant or breast feeding
- 3. Concomitant uncontrolled serious medical conditions
- 4. Severe renal or hepatic impairment not related to lymphoma
- 5. Known hypersensitivity to murine proteins
- 6. Previous malignancy in the last 5 years (except non-melanomatous skin tumours and carcinoma in situ of the cervix)
- 7. Psychological illness or condition that prevents adequate trial compliance

Date of first enrolment

01/10/2002

Date of final enrolment

22/02/2005

Locations

Countries of recruitment

Australia

England

United Kingdom

Study participating centre
Cancer Sciences Building, MP 824
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation

University College London (UK)

Sponsor details

Cancer Research UK & UCL Cancer Trials Centre (CTC) 90 Tottenham Court Road London England United Kingdom W1T 4TJ

Sponsor type

University/education

Website

http://www.ucl.ac.uk/cancertrials/

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Government

Funder Name

Southampton University Hospitals NHS Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2016		Yes	No