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

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

**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**
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 |