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

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
30/11/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00053092

Clinical Trials Information System (CTIS)
2005-003178-71

Protocol serial number
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

Study type(s)
Treatment

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(s)
1. Response rate
2. Time to disease progression
3. Toxicity
4. Overall survival

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Australia

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

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Southampton University Hospitals NHS Trust (UK)

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	01/02/2016		Yes	No