

Randomised Controlled Trial of CID versus CD for Induction of Remission in Low Grade Non-Hodgkin's Lymphoma and Randomised Controlled Assessment of Interferon as Maintenance Treatment after Remission Induction

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 30/11/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SNLG NHLVIII

Study information

Scientific Title

Randomised Controlled Trial of CID versus CD for Induction of Remission in Low Grade Non-Hodgkin's Lymphoma and Randomised Controlled Assessment of Interferon as Maintenance Treatment after Remission Induction

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

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Lymphoma (non-Hodgkin's)

Interventions

INDUCTION / CONSOLIDATION:

Patients are randomised to one of two treatment arms:

1. Arm A: Chemotherapy with Chlorambucil, idarubicin and dexamethasone (CID), cycle to be repeated every 21 days. Patients showing a response following three courses will receive three further consolidation courses.
2. Arm B: Chemotherapy with Chlorambucil and dexamethasone (CD), cycle to be repeated every

21 days. Patients showing a response following three courses will receive three further consolidation courses.

RADIOTHERAPY: Patients may be given localised radiotherapy to initial areas of bulky disease if a complete response in that particular site has not been obtained following induction.

MAINTENANCE: Patients who have shown a complete response or good partial response following six cycles of induction therapy are eligible for the second randomisation. Patients are randomised to one of three groups:

1. Group A: No further therapy.
2. Group B: Low dose interferon, 1MU subcutaneously three times a week until progression or maximum of 36 months.
3. Group C: High dose interferon, 3MU subcutaneously three times a week until progression or maximum of 36 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1995

Completion date

30/06/2000

Eligibility

Key inclusion criteria

1. Kiel classification of low grade non-Hodgkin's lymphoma
2. Stages II to IV
3. Age 15 to 70 years
4. Measurable disease
5. No prior chemotherapy
6. No central nervous system (CNS) involvement
7. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
8. Adequate bone marrow, renal and hepatic function
9. No medical contraindications to protocol treatments

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1995

Date of final enrolment

30/06/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Scotland & Newcastle Lymphoma Group (UK)

Sponsor details

Medical Statistics Unit, Department of Public Health Sciences

University of Edinburgh

Medical School

Teviot Place

Edinburgh

United Kingdom

EH8 9AG

+44 (0)131 650 4382

jim.wilson@ed.ac.u

Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Scottish & Newcastle Lymphoma Group (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	01/11/2006		Yes	No