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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 30/11/2015	**Condition category** Cancer	

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