ISRCTN46751362 https://doi.org/10.1186/ISRCTN46751362

A European randomised multicentre study of interferon alpha-2b versus no treatment after intensive therapy and Autologous hematopoeitic Stem Cell Transplantation (ASCT) for relapsing lymphoma patients

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 14/07/2014	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

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

Protocol serial number
LY302

Study information

Scientific Title

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

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Lymphoma (Hodgkin's), Lymphoma (non-Hodgkin's)

Interventions
Patients are randomised to one of two treatment groups:
Group A: High dose therapy with ASCT, then after haematologic recovery, no further treatment.
Group B: High dose therapy with ASCT, then after haematologic recovery, interferon alpha-2b 2MU subcutaneously three times weekly for the first four weeks then 3MU three times weekly for 17 months. The interferon dose will be modified according to haematologic tolerance.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/01/2000

Eligibility

Key inclusion criteria

1. Patients with histologically proven non-Hodgkin's lymphoma or Hodgkin's disease, in first relapse or first progression responding to salvage regimen, and treated with high dose therapy and ASCT
2. Normal renal and hepatic function.
3. Eastern Cooperative Oncology Group (ECOG) performance status zero to three
4. Aged 18 to 65 years
5. No history of prior or concomitant malignancy except for treated (surgery or radiotherapy) basal cell carcinoma of the skin or carcinoma in situ, whatever the site

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1999

Date of final enrolment
01/01/2000

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Schering-Plough Ltd (UK)

ROR
https://ror.org/00148fb49

Funder(s)

Funder type
Industry

Funder Name
Schering-Plough Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration