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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1999

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

Age group
Not Specified

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
01/01/1999

Date of final enrolment
01/01/2000

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Schering-Plough Ltd (UK)

Sponsor details
Schering-Plough House
Shire Park
Welwyn Garden City
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AL7 1TW

Sponsor type
Industry

ROR
https://ror.org/00148fb49

Funder(s)

Funder type
Industry

Funder Name
Schering-Plough Ltd (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