

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

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 type="checkbox"/> Results
Last Edited 14/07/2014	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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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
United Kingdom
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