

Marrow-ablative chemotherapy and autologous stem cell transplantation followed by interferon-alpha maintenance treatment versus interferon-alpha maintenance treatment alone for stage III and IV follicular Non-Hodgkin's lymphoma

Submission date 19/08/2002	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 19/08/2002	Overall study status Stopped	☐ Statistical analysis plan ☒ Results
Last Edited 16/04/2019	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

ClinicalTrials.gov (NCT)
NCT00003152

Protocol serial number

EORTC 20963

Study information

Scientific Title

Marrow-ablative chemotherapy and autologous stem cell transplantation followed by interferon-alpha maintenance treatment versus interferon-alpha maintenance treatment alone for stage III and IV follicular Non-Hodgkin's lymphoma

Study objectives

Added 07/08/09:

Interferon alpha may interfere with the growth of cancer cells. Radiation therapy uses high-energy x-rays to damage cancer cells. Peripheral stem cell transplantation may allow the doctor to give higher doses of chemotherapy drugs and radiation therapy and kill more cancer cells. The aim of this trial is to compare the effectiveness of combination chemotherapy followed by interferon alfa alone versus combination chemotherapy plus radiation therapy and peripheral stem cell transplantation in treating patients who have previously untreated stage III or stage IV follicular non-Hodgkin's lymphoma.

As of 07/08/09 this record has been extensively updated. All updates can be found under the relevant field with the above update date. Please also note that the start date of this trial have been changed from 01/01/1999 as this date was automatically generated on registration.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre randomised active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lymphoma (non-Hodgkin's)

Interventions

1. All patients receive induction chemotherapy with cyclophosphamide, vincristine and prednisolone (CVP) repeated every 21 days for eight cycles.
2. Patients who achieve a complete remission or partial remission with a limited bone marrow infiltration will be randomised to one of the two arms of the protocol:
 - 2.1. Arm A: Maintenance treatment with interferon-alpha, 3MU three times weekly until disease progression or relapse (a maximum period of three years).
 - 2.2. Arm B: Patients receive cyclophosphamide priming and peripheral blood stem cell harvest

followed by marrow-ablative chemo-radiotherapy. Marrow-ablative chemo-radiotherapy consists of high-dose cyclophosphamide and total body irradiation at a total dose of 9 Gy to the midline of the body plus peripheral blood stem cell reinfusion. Maintenance treatment with interferon-alpha, 3MU three times weekly is given until disease progression or relapse (a maximum period of three years).

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Cyclophosphamide, vincristine and prednisolone (CVP), interferon-alpha.

Primary outcome(s)

Added 07/08/09:

1. Progression free and overall survival
 2. Toxicity
 3. Mortality
- Patients are followed every 4 months until death.

Key secondary outcome(s)

Not provided at time of registration

Completion date

15/11/1999

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

Current information as of 07/08/09:

1. Previously untreated follicular non-Hodgkin's lymphoma presenting with stages III or IV, including nodal, Waldeyers ring and extranodal locations - at least one measurable mass should be present
2. Above 18 years and below 66 years
3. World Health Organisation (WHO) performance status zero to two
4. Alkaline phosphatase and bilirubin less than 2.5 times upper limit of normal (ULN) (unless clearly related to NHL)
5. Creatinine and BUN less than 2.5 times ULN (unless clearly related to NHL)

Initial information at registration:

1. Previously untreated follicular non-Hodgkin's lymphoma presenting with stages III or IV, including nodal, Waldeyers ring and extranodal locations - at least one measurable mass should be present
2. Above 18 years and below 66 years
3. World Health Organisation (WHO) performance status zero to two

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Current information as of 07/08/09:

1. Prior malignancies except non-melanoma skin tumours or stage 0 in situ cervical carcinoma
2. Severe cardiac disease (e.g. severe heart failure requiring treatment or cardiac ejection fraction less than 45%)
3. Neurologic disease
4. Pulmonary disease
5. Psychiatric or metabolic disease
6. HIV positive
7. Pregnancy
8. Other medical contraindications to protocol treatments

Initial information at registration

1. Prior malignancies except non-melanoma skin tumours or stage 0 in situ cervical carcinoma
2. Other medical contraindications to protocol treatments

Date of first enrolment

28/03/1997

Date of final enrolment

15/11/1999

Locations**Countries of recruitment**

United Kingdom

England

Netherlands

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom
NW1 2DA

Sponsor information

Organisation

European Organisation for Research and Treatment of Cancer (EORTC) (Belgium)

ROR

<https://ror.org/034wxcc35>

Funder(s)

Funder type

Research organisation

Funder Name

Added 07/08/09:

Funder Name

European Organization for Research and Treatment of Cancer (EORTC) (ref: 20963)

Results and Publications

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	01/01/1998	16/04/2019	Yes	No