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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 [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/08/2002	**Overall study status** Stopped	
Last Edited 16/04/2019	**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
NCT00003152

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 cylophosphamide 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 measure
Added 07/08/09:
1. Progression free and overall survival
2. Toxicity
3. Mortality
Patients are followed every 4 months until death.

Secondary outcome measures
Not provided at time of registration

Overall study start date
28/03/1997

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
469 patients will be accrued for this study within 5 years (added 07/08/09)

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
England

Netherlands

United Kingdom

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)

Sponsor details
83, Avenue E. Mounier
Bte 11
Brussels
Belgium
B-1200
+32 2 774 16 41
eortc@eortc.be

Sponsor type
Research organisation

Website
http://www.eortc.be

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

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