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Intensified CHOP of 12-weeks duration plus G-CSF as compared with standard CHOP of 24-weeks duration for patients with intermediate prognosis non-Hodgkin's lymphoma

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
09/11/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr L F Verdonck

Contact details
University Medical Centre Utrecht
Department of Haematology
P.O. Box 85500
Utrecht
Netherlands
3508 GA
+31 (0)30 250 7230
l.f.verdonck@azu.nl

Additional identifiers

Protocol serial number
Ho26

Study information

Scientific Title
Intensified CHOP of 12-weeks duration plus G-CSF as compared with standard CHOP of 24-weeks duration for patients with intermediate prognosis non-Hodgkin's lymphoma

Acronym
HOVON 26 NHL

Study objectives
The hypothesis to be tested is that the outcome in arm B is better than in arm A.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Primary study design
Interventional

Study design
Randomised, placebo controlled, parallel group, multicentre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non Hodgkin's lymphoma (NHL)

Interventions
Patients will be randomised between:
Arm A: Three courses of standard cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) every three weeks.
Arm B: Three courses of intensified CHOP every two weeks plus Granulocyte-Colony Stimulating Factor (G-CSF).

Patients with less than Partial Response (PR) will go off protocol. Patients in PR or Complete Response (CR) will proceed to another five courses of standard CHOP or another three courses of intensified CHOP plus G-CSF.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), and Granulocyte-Colony Stimulating Factor (G-CSF).

Primary outcome(s)

CR rate and overall survival.

Key secondary outcome(s)
1. Disease-free survival
2. Relapse rate
3. Assessment of value of risk factors at diagnosis in relation to dose intensity of the treatment
4. Morbidity, number of days in hospital, treatment-related mortality, duration of leucopenia and other aspects in relation to dose intensity

Completion date
01/04/2004

Eligibility

Key inclusion criteria
1. Previously untreated patients with a primary Non Hodgkins Lymphoma (NHL) of intermediate or high grade malignancy according to the Working Formulation (group D, E, F, G, H)
2. Belonging to the intermediate risk group:
a. stage II, Lactate Dehydrogenase (LDH) greater than or equal to 1.5 x normal
b. stage III, LDH greater than 1.5 x normal
c. stage IV, LDH less than 1.5 x normal
3. Age greater than or equal to 15, or less than or equal to 65 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
477

Key exclusion criteria
1. Patients with prior malignancies, except stage one cervix carcinoma and basocellular carcinoma
2. Patients with severe cardiac (means severe heart failure requiring symptomatic treatment or a cardiac ejection fraction of less than 45%) pulmonary, neurologic or metabolic disease.
3. Inadequate liver or renal function i.e. serum creatinine or bilirubin greater than 25 x the upper normal value, except when related to the lymphoma
4. Human Immunodeficiency Virus (HIV) positivity
5. Inability to give informed consent
6. Involvement of the central nervous system by the NHL

Date of first enrolment

11/11/1994

Date of final enrolment
01/04/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
Daniel den Hoed Kliniek (Erasmus Medical Centre) (The Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Research organisation

Funder Name
Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (The Netherlands)

Funder Name
The National Cancer Fund (Koningin Wilhelmina Fonds [KWF]) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		01/04/2007		Yes	No