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Randomized phase III study of Rituximab with intensified CHOP chemotherapy versus Rituximab with High-Dose Sequential Therapy and Autologous Stem Cell Transplantation in Adult Patients (18-65 years) with Stage II-IV High-intermediate or High Risk DLBCL

Submission date
13/01/2006

Recruitment status
No longer recruiting

Registration date
13/01/2006

Overall study status
Completed

Last Edited
24/07/2014

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Protocol serial number

HO63

Study information

Scientific Title

Acronym
HOVON 63 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)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients will be randomized between:
Arm A: 6 cycles of rituximab-iCHOP every 2 weeks plus G-CSF: pegfilgrastim (Neulasta®)
Arm B: 3 cycles of rituximab-iCHOP every 2 weeks plus G-CSF: pegfilgrastim (Neulasta®), followed by rituximab-HDT Induction I, rituximab-HDT Induction II plus daily G-CSF: filgrastim (Neupogen®, SingleJect®), followed by BEAM with ASCT. Daily G-CSF: filgrastim (Neupogen® SingleJect®) will replace pegfilgrastim in the iCHOP chemotherapy cycle during which stem cells will be harvested.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Rituximab, CHOP

Primary outcome(s)

Event-free survival i.e. time from registration to induction failure (less than PR after 3 x R-iCHOP, no CR [Cru] after 6 RiCHOP [arm A] or ASCT [arm B]), death, progression or relapse whichever occurs first; the time to failure of patients with induction failure (less than PR after 3 x R-iCHOP) is set at one day.

Key secondary outcome(s))
1. Complete response (including CRu)
2. Progression on protocol (progression or relapse after initial PR or CR during protocol treatment)
3. Overall survival measured form the time of registration
4. Disease-free interval (duration of the first CR) measured from the time of achievement of CR (including CRu) after protocol treatment to day of relapse or death from any cause (whichever occurs first)

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Patients with a confirmed histologic diagnosis of DLBCL according to the WHO classification
2. Ann Arbor stage II-IV
3. High-intermediate or high risk NHL according to age-adjusted IPI score (aa IPI = 2-3)
4. DLBCL must be CD20 positive
5. Age 18-65 years inclusive
6. WHO performance status </= 2
7. Negative pregnancy test (if applicable)
8. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Intolerance of exogenous protein administration
2. Severe cardiac dysfunction (NYHA classification II-IV) or LVEF <45%

3. Significant renal dysfunction (serum creatinine >/= 150 mumol/l), unless related to NHL
4. Significant hepatic dysfunction (total bilirubin >/= 30 mumol/l or
transaminases >/= 2.5 times normal level), unless related to NHL
5. Suspected or documented Central Nervous System involvement by NHL
6. Testicular DLBCL
7. Primary mediastinal B cell lymphoma
8. Patients known to be HIV-positive
9. Patients with active, uncontrolled infections
10. Patients with uncontrolled asthma or allergy, requiring steroid treatment
11. Patient is a lactating woman
12. Unwillingness or not capable to use effective means of contraconception (all men and pre-menopausal women)
13. Prior treatment with chemotherapy, radiotherapy or immunotherapy for this lymphoma, except a short course of prednisone (<1 week) and/or cyclophosphamide (<1 week and not in excess of 900 mg/m2 cumulative) or local radiotherapy in order to control life threatening tumor related symptoms
14. History of active cancer during the past 5 years, except basal carcinoma of the skin or stage 0 cervical carcinoma

Date of first enrolment
28/10/2005

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
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Sponsor information

Organisation
Dutch Haemato-oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON)

ROR
https://ror.org/056kpdx27

Funder(s)

Funder type
Industry

Funder Name
Amgen, Johnson & Johnson - Orthobiotech, Dutch Cancer Society, Novartis Pharma B.V., Roche Nederland BV

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration