

# 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

<b>Submission date</b> 13/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year
<b>Registration date</b> 13/01/2006	<b>Overall study status</b> Completed	
<b>Last Edited</b> 24/07/2014	<b>Condition category</b> Cancer	

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

**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 measure**

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.

## **Secondary outcome measures**

1. Complete response (including CRu)
2. Progression on protocol (progression or relapse after initial PR or CR during protocol treatment)
3. Overall survival measured from 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)

## **Overall study start date**

28/10/2005

## **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  $\leq 2$
7. Negative pregnancy test (if applicable)
8. Written informed consent

## **Participant type(s)**

Patient

## **Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

250

**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  $\geq 150$   $\mu\text{mol/l}$ ), unless related to NHL
4. Significant hepatic dysfunction (total bilirubin  $\geq 30$   $\mu\text{mol/l}$  or transaminases  $\geq 2.5$  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 contraception (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/m<sup>2</sup> 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**  
Groningen  
Netherlands  
9700 RB

## **Sponsor information**

### **Organisation**

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

### **Sponsor details**

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### **Sponsor type**

Research organisation

### **Website**

<http://www.hovon.nl/>

### **ROR**

<https://ror.org/056kpx27>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

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

## **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