# 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.

No registrations found.

**Ethical review** Positive opinion

**Status** Recruitment stopped

Health condition type -

Study type Interventional

## **Summary**

#### ID

NL-OMON28643

Source

NTR

**Brief title** 

**HOVON 26 NHL** 

**Health condition** 

Non Hodgkin's Lymphoma.

## **Sponsors and support**

**Primary sponsor:** Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)

P/a HOVON Data Center

Erasmus MC - Daniel den Hoed

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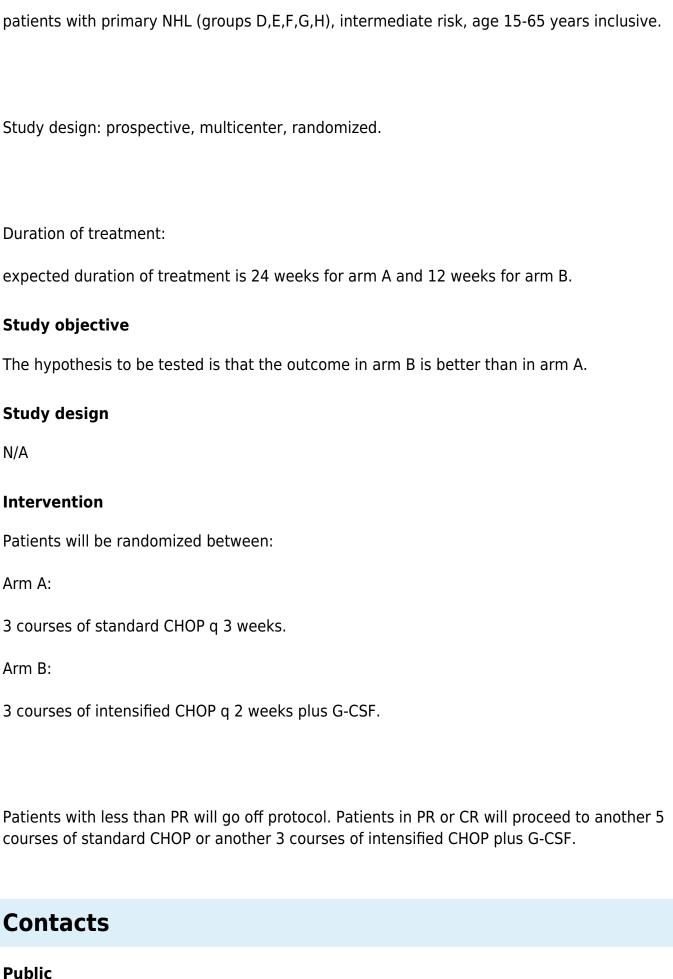
Source(s) of monetary or material Support: Stichting Hemato-Oncologie voor

Volwassenen Nederland (HOVON) Koningin Wilhelmina Fonds (KWF) Intervention **Outcome measures Primary outcome** CR rate and overall survival. **Secondary outcome** 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, nr of days in hospital, treatment-related mortality, duration of leucopenia and other aspects in relation to dose intensity. **Study description Background summary** Study phase: phase III.

Study objective:

evaluation of the effect of intensified CHOP q 2 weeks + G-CSF with respect to CR rate and disease-free and overall survival.

Patient population:



#### Public

University Medical Center Utrecht (UMCU),

3 - Intensified CHOP of 12-weeks duration plus G-CSF as compared with standard CHOP ... 9-05-2025

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#### **Scientific**

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# **Eligibility criteria**

#### Inclusion criteria

- 1. Previously untreated patients with a primary 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: stage II, LDH >=1.5x normal; stage III, LDH >1.5x normal; stage IV, LDH <1.5x normal;
- 3. Age >=15 <=65 years.

## **Exclusion criteria**

- 1. Patients with prior malignancies, except stage 1 cervix carcinoma and basocellular carcinoma:
- 2. Patients with severe cardiac (means severe heart failure requiring symptomatic treatment or a cardiac ejection fraction of < 45%) pulmonary, neurologic or metabolic disease-lnadequate liver or renal function, i.e. serum creatinine or bilirubin > 2.5x the upper normal value, except when related to the lymphoma;
- 3. HIV positivity;
- 4. Inability to give informed consent;

5. Involvement of the central nervous system by the NHL.

# Study design

## **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Placebo

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 11-11-1994

Enrollment: 513

Type: Actual

# **Ethics review**

Positive opinion

Date: 06-09-2005

Application type: First submission

# **Study registrations**

## Followed up by the following (possibly more current) registration

No registrations found.

# Other (possibly less up-to-date) registrations in this register

No registrations found.

# In other registers

RegisterIDNTR-newNL202NTR-oldNTR239Other: Ho26

ISRCTN ISRCTN11397785

# **Study results**

## **Summary results**

Blood. 2007 Apr 1;109(7):2759-66.