A randomized phase III study of chimeric anti-CD20 monoclonal antibody (Rituximab) with 2-weekly CHOP chemotherapy (CHOP 14) in elderly patients with intermediate- or high-risk non-Hodgkin’s lymphoma.

Gepubliceerd: 05-09-2005 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28411

Bron
NTR

Verkorte titel
HOVON 46 NHL

Aandoening

Non Hodgkin’s Lymphoma

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
Erasmus MC - Daniel den Hoed
Postbus 5201
3008 AE Rotterdam
Tel: 010 4391568

Fax: 010 4391028
e-mail: hdc@erasmusmc.nl
Overige ondersteuning: - Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
- Koningin Wilhelmina Fonds (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Event-free survival (i.e. time from registration to induction failure (i.e. no CR or CRu on induction treatment), death or relapse whichever occurs first); the time to failure of patients with induction failure is set at one day.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase: phase III

Study objective: evaluation of the effect of anti-CD20 (Rituximab) combined with 2-weekly CHOP + G-CSF in comparison to 2-weekly CHOP + G-CSF alone

Patient population: patients with intermediate- or high-risk NHL (MCL, Follicular Lymphoma grade III or DLBCL), CD20-positive, previously untreated, age >= 65 years and good WHO performance status (WHO 0-2)

Study design: prospective, multicenter, randomized

Duration of treatment: expected duration of treatment is 16 weeks.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients will be randomized between:

Arm A:
8 cycles of CHOP q 2 weeks plus G-CSF (pegfilgrastim, Neulasta®) once per cycle;

Arm B:
8 cycles of CHOP q 2 weeks plus G-CSF (pegfilgrastim, Neulasta®) once per cycle combined with 6 administrations of Rituximab (Mabthera®).

Contactpersonen

Publiek

P.O. Box 2040
P. Sonneveld
Erasmus University Medical Center,
Department of Hematology
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033589

Wetenschappelijk

P.O. Box 2040
P. Sonneveld
Erasmus University Medical Center,
Department of Hematology
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033589

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with a confirmed histologic diagnosis of NHL according to the WHO classification: Mantle cell lymphoma (MCL), Follicular lymphoma (grade III) (FL III) or Diffuse large B-cell lymphoma (DLBCL);

2. Low-intermediate, high-intermediate or high risk NHL according to age-adjusted IPI score;

3. NHL must be CD20 positive;

4. Age 65 years or more;

5. WHO performance status 0-2;

6. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Intolerance of exogenous protein administration;

2. Severe cardiac dysfunction (NYHA classification II-IV) or LVEF < 45 %;

3. Significant renal dysfunction (serum creatinine >= 150 mmol/l), unless related to NHL;

4. Significant hepatic dysfunction (total bilirubin >= 30 mmol/l or transaminases >= 2.5 times normal level), unless related to NHL;

5. Suspected or documented Central Nervous System involvement by NHL;

6. Patients known to be HIV-positive;

7. Patients with active, uncontrolled infections;

8. Patients with uncontrolled asthma or allergy, requiring steroid treatment

ior treatment with chemotherapy, radiotherapy or immunotherapy for this lymphoma, except local radiotherapy in case of (potential) organ dysfunction by localized lymphoma mass or infiltration

story of active cancer during the past 5 years, except basal carcinoma of the skin or stage 0 cervical carcinoma.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	28-11-2001
Aantal proefpersonen:	400
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL149
NTR-old	NTR184
Ander register	: Ho46
ISRCTN	ISRCTN84611849

Resultaten

Samenvatting resultaten
N/A