Phase II study on the feasibility and efficacy of R-DHAP + HD-MTX, combined with intrathecal rituximab, followed by autologous stem cell transplantation in patients with a recurrent aggressive B-cell lymphoma with CNS localisation.

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The hypothesis to be tested is that treatment with three courses of R-DHAP + MTX combined with rituximab i.t., followed by ASCT is feasible and that the efficacy meets the expectations as described in the protocol.

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

Samenvatting

ID

NL-OMON23427

Bron
NTR

Verkorte titel
HOVON 80 NHL

Aandoening

Recurrent aggressive B-cell lymphoma with CNS localisation, DLBCL, non-hodgkin lymphoma, NHL

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
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Overige ondersteuning: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON), Koningin Wilhelmina Fonds (KWF), Roche

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Progression-free survival measured from the date of registration. Patients still alive or lost to follow up are censored at the last day they were known to be alive.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase:
Phase II

Study objective:
Evaluation of intensive therapy for relapsed B-cell lymphoma with CNS localisation.

Treatment includes:

A. Intrathecal administration of rituximab
B. Combining R-DHAP with high dose methotrexate intravenously.

The following endpoints will be evaluated:
Progression free survival, response rate and overall survival.

Patient population:
Patients with CD20 positive lymphoma (DLBCL, follicular lymphoma grade 3) in first relapse or progression, with central nervous system involvement with or without systemic disease, age 18-65 years inclusive.

Study design:
Prospective multicenter

Duration of treatment:
Expected duration of 5 months. All patients will be followed until 5 years after registration.

Doel van het onderzoek

The hypothesis to be tested is that treatment with three courses of R-DHAP + MTX combined with rituximab i.t., followed by ASCT is feasible and that the efficacy meets the expectations as described in the protocol.

Onderzoeksopzet

At entry, after cycle 2, after cycle 3, after Tx, after RT (if applicable), in FU every 3 months during first 2 years, every 6 months during the next 2 years and annually thereafter (until total of 5 years).

Onderzoeksproduct en/of interventie

Three cycles of R-DHAP + MTX and rituximab i.t., followed by ASCT.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosis of aggressive malignant B-cell lymphoma based upon a representative histology specimen according to the WHO classification:

A. Follicular lymphoma grade III;

B. Diffuse large B-cell lymphoma;

C. Prior 'low-grade' lymphoma with histologically proven transformation to follicular lymphoma grade III or DLBCL is also permitted.

2. CD 20 positive;

3. First progression or relapse with CNS localisation (see below) without or with systemic relapse (preferably histologically proven). 'Progressive' includes patients who have progressive disease (PD), without prior response and patients who have progression after first PR;

4. Diagnosis of CNS localisation based on at least one of the following:

A. Unequivocal morphological and/or immunophenotypical evidence of CSF lymphoma;

B. Clinical AND MRI evidence of leptomeningeal localisation;

C. Brain parenchymal lesion showing homogeneous contrast enhancement suspect for lymphoma, concurrently with systemic progression or recurrence;

D Biopsy-proven brain parenchymal NHL localisation of previously diagnosed systemic NHL.

5. Age 18-65 years inclusive;

6. WHO performance status 0 ¨C 2 with or without administration of steroids;

7. Written informed consent according to the centre's requirements;

8. Negative pregnancy test in women of reproductive potential.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of intolerance of exogenous protein administration;

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

3. Severe pulmonary dysfunction (vital capacity or diffusion capacity < 50% of predicted value) unless clearly related to NHL involvement;

4. Hepatic dysfunction, bilirubin or transaminase ¡Ý 2.5 x upper normal limit, unless related to lymphoma;

5. Renal dysfunction (serum creatinine >150 umol/l or clearance < 60 ml/min);

6. Prior cranial radiotherapy;

7. Active uncontrolled infection;

8. Known HIV-positivity;

9. (EBV) post-transplant lymphoproliferative disorder.

Documented CNS involvement during 1st line therapy (MTX intrathecal profylaxis during 1st line therapy is no exclusion criterium).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-10-2006
Aantal proefpersonen:	35
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-04-2009
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	NL1659
NTR-old	NTR1757
Ander register	EudraCT number : 2006-002141-37
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A