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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23427

Source
Nationaal Trial Register

Brief title
HOVON 80 NHL

Health condition

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

Sponsors and support

Primary 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 7041560

Fax: 010 7041028
e-mail: hdc@erasmusmc.nl
Source(s) of monetary or material Support: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON), Koningin Wilhelmina Fonds (KWF), Roche

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Response to R-DHAP-MTX;

2. Overall survival;

3. Toxicity;

4. Percentage of patients transplanted.

Study description

Background summary

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.

Study objective

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.

Study design

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).

Intervention

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

Contacts

Public
Erasmus MC - Daniel den Hoed
Afd. Neurologie
Postbus 5201

J.E.C. Bromberg
Rotterdam 3008 AE
The Netherlands
+31 (0)10 7041911
Scientific
Erasmus MC - Daniel den Hoed

Afd. Neurologie
Postbus 5201

J.E.C. Bromberg
Rotterdam 3008 AE
The Netherlands
+31 (0)10 7041911

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-10-2006
Enrollment:	35
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-04-2009
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

Register	ID
NTR-new	NL1659
NTR-old	NTR1757
Other	EudraCT number : 2006-002141-37
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A