A randomized phase III study to evaluate the efficacy of chemoimmunotherapy with the monoclonal antibody Campath-1H (Alemtuzumab) given in combination with 2-weekly CHOP versus 2-weekly CHOP alone in elderly patients with previously untreated systemic peripheral T-cell lymphomas

Published: 06-06-2008
Last updated: 11-05-2024

See C4

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas non-Hodgkin's T-cell
Study type	Interventional

Summary

ID

NL-OMON41578

Source
ToetsingOnline

Brief title
HOVON 91 T-NHL / ACT-2 trial

Condition

- Lymphomas non-Hodgkin's T-cell

Synonym
T-cell lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: University Medicine Goettingen
Source(s) of monetary or material Support: HOVON + KWF (datamanagement)

Intervention

Keyword: Alemtuzumab, peripheral T cell lymphoma, phase III trial, T-cell non-Hodgkin's lymphoma

Outcome measures

Primary outcome

event-free survival at 3 yr

Secondary outcome

overall survival at 3 yr

progression-free survival at 3 yr

responses (%CR and %PR), at the end of therapy

time to progression

relation CD52 expression and response-rate

safety addition of alemtuzumab to CHOP measured by incidences of infections

Study description

Background summary

see C4

Study objective

See C4

Study design

Intergroup design, multicenter randomised fase III study

Intervention

The addition of alemtuzumab to standard CHOP chemotherapy, see above

Study burden and risks

standard treatment consists of CHOP, given at 2 weeks interval. The addition of alemtuzumab requires subcutaneous injections at day 1 and 2. The first 2 injections can cause transient painful infiltrates. The risk on infections is increased requiring additional antibiotics and blood controls, especially related to CMV re-activations. Blood products need to be irradiated.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age: 61 - 80 years
2. All risk groups, including stage I with bulk (>= 7.5 cm) and stages II to IV, except stage I with no further IPI risk factor (LDH, ECOG, stage, E>1) beside the age over 60
3. Confirmed histological diagnosis of peripheral T cell NHL of the following types:
peripheral T-cell lymphoma PTCL-NOS
Angioimmunoblastic T cell lymphoma
intestinal T/NK-cell lymphoma (± enteropathy)
hepatosplenic lymphoma
subcutaneous panniculitis-like PTCL (gamma-delta T-cell lymphoma)
4. Performance status: ECOG 0 - 2 (Karnofsky index: 60 - 100%). ECOG 3 is acceptable, if lymphoma related.
5. Measurable disease
6. written consent of the patient

Exclusion criteria

1. Stage I with IPI 0 and without bulk
2. Already initiated lymphoma therapy
3. Serious accompanying disorder or impaired organ function, in particular:
- severe cardiac dysfunction (NYHA class II-IV; LVEF <45%)
- severe pulmonary dysfunction (FeV1<50% or DC <50%)
- Renal: creatinine >2 times the upper reference limit, unless related to NHL
- Hepatic: bilirubin >2 times the upper reference limit, unless related to NHL
- Uncontrollable diabetes mellitus (prephase treatment with prednisone!)
4. Platelets <100 000/mm3, leukocytes <2500/mm3
5. Bone marrow involvement >25%
6. Known hypersensitivity to the medications to be used, especially murine or chimeric antibodies
7. primary leukemic lymphoma
8. Known HIV-positivity
9. Active hepatitis infection, active CMV infection, active systemic fungal infection, active infection with mycobacterium tuberculosis or atypical tuberculosis
10. Suspicion that patient compliance will be poor
11. Simultaneous participation in any other study protocol
12. Prior chemo- or radiotherapy for malignancy
13. Other concomitant malignant disease (history of active cancer during the past 5 years, except basal carcinoma of the skin or stage 0 cervical carcinoma)

14. Non-conformity to eligibility criteria

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-04-2009
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	MabCampath
Generic name:	Alemtuzumab; Monoclonal antibody Campath-1H
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	06-06-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-11-2008

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-03-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-04-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-04-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-07-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-09-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2007-000821-23-NL
CCMO	NL18527.042.08