Phase 3 trial of the antiangiogenic agent thalidomide in patients with malignant mesothelioma after first line chemotherapy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24002

Source
NTR

Brief title
NVALT5

Health condition

Stabilisation or response to first line chemotherapy including pemetrexed.
Patients randomized in the obeservation arm will only receive best supportive care

Sponsors and support

Primary sponsor: NVALT
Source(s) of monetary or material Support: One time financial support for manufacturing of thalidomide by Eli Lilly Corp.
Thalidomide is prepared by Prof J Beijnen farmacist, the Slotervaart hospital

Intervention

Outcome measures

Primary outcome

Increase of 5 to 7.5 moths for time to recurrence.

Secondary outcome

Toxicity (neurologic and thrombo-embolic)

Study description

Background summary

In a phasee 2 study of patients with progressive mesothelioma, 27% showed stabilization of disease for more than 6 months. Therefore a phase 3 randomized study was developed to investigate the true gain of daily thalidomide in patients who have had no signs of progression of the disease after standard first line therapy. The hypothesis is that thalidomide is able to delay the revascularization of mesotheliomas. These are known for their high expression of VEGF and worse prognosis when a high vessel density is observed.

Study objective

Maintenance thalidomide delays the time to progression with 50% in patients who do not progress after > 3 cycles of pemetrexed containing chemotherapy.

Intervention

Thalidomide 200 mg orally at night for up to 1 year with best supportive care
or observation alone with best supportive care.

Contacts

Public
The Netherlands Cancer center
NVALT Trial Desk
Plesmanlaan 121
D. Storm
Amsterdam 1066 CX
The Netherlands
+31(0)20 5129111

Scientific
The Netherlands Cancer center
NVALT Trial Desk
Plesmanlaan 121
D. Storm
Amsterdam 1066 CX
The Netherlands
+31(0)20 5129111

Eligibility criteria

Inclusion criteria

1. Good condition (PS 0-2);

2. First line therapy with pemetrexed minimum of 4 courses;

3. A measurable lesion is not required;

4. Normal laboratory values;

5. Signed informed consent;

6. Thalidomide therapy to start within 9 weeks after last chemotherapy course.

Exclusion criteria

1. Inaqdequate measures for birth control;

2. Polyneuropathy > grade 1;

3. Thrombo-embolic events.

Study design

Design

Study type: Interventional

Intervention model:	Factorial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-09-2004
Enrollment:	216
Type:	Actual

Ethics review

Positive opinion

Date:	01-10-2006
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	NL786
NTR-old	NTR798
Other	: N/A
ISRCTN	ISRCTN13632914

Study results

Summary results
only on phase 2 study by P Baas et al 2005 Lung Cancer