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

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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

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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.

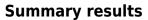
In other registers

Register ID

NTR-new NL786 NTR-old NTR798 Other : N/A

ISRCTN ISRCTN13632914

Study results



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