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

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

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

Samenvatting

ID

NL-OMON24002

Bron
Nationaal Trial Register

Verkorte titel
NVALT5

Aandoening

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

Ondersteuning

Primaire sponsor: NVALT
Overige ondersteuning: One time financial support for manufacturing of thalidomide by Eli Lilly Corp.
Thalidomide is prepared by Prof J Beijnen farmacist, the Slotervaart hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Increase of 5 to 7.5 moths for time to recurrence.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Inaqdequate measures for birth control;

2. Polyneuropathy > grade 1;

3. Thrombo-embolic events.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	09-09-2004
Aantal proefpersonen:	216
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	01-10-2006
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	NL786
NTR-old	NTR798

Register	ID
Ander register	: N/A
ISRCTN	ISRCTN13632914

Resultaten

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