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Phase III trial of the anti-angiogenic agent thalidomide in patients with malignant mesothelioma after first line chemotherapy

Submission date 28/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 03/07/2013	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
NVALT5

Study objectives
Maintenance thalidomide delays the time to progression with 50% in patients who do not progress after more than three cycles of pemetrexed containing chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics board (De Protocol Toetsingscommissie van het Nederlands Kanker Instituut Antoni van Leeuwenhoek Ziekenhuis [PTC]) on the 14th January 2004 (ref: PTC04.074).

Study design
Randomised, controlled, factorial, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Malignant mesothelioma

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

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Thalidomide

Primary outcome measure
Increase of five to 7.5 months for time to recurrence.

Secondary outcome measures
Toxicity (neurologic and thrombo-embolic).

Overall study start date
09/09/2004

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Good condition (Eastern Cooperative Oncology Group [ECOG] Performance Status [PS] zero to two)
2. First line therapy with pemetrexed minimum of four courses
3. A measurable lesion is not required
4. Normal laboratory values
5. Signed informed consent
6. Thalidomide therapy to start within nine weeks after last chemotherapy course

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
216

Key exclusion criteria
1. Inaqdequate measures for birth control
2. Polyneuropathy more than grade one
3. Thrombo-embolic events

Date of first enrolment
09/09/2004

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
The Netherlands Cancer Center
Amsterdam
Netherlands
1066 CX

Sponsor information

Organisation
Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose (NVALT) (The Netherlands)

Sponsor details
Luijbenstraat 15
Den Bosch
Netherlands
5211 BR
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Sponsor type
Research organisation

Website
http://www.nvalt.nl/

ROR
https://ror.org/03a3n5193

Funder(s)

Funder type
Industry

Funder Name
Eli Lilly (The Netherlands)

Funder Name
Thalidomide is prepared by Professor J Beijnen, pharmacist, The Slotervaart Hospital (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2013		Yes	No