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A randomised phase II study of doxorubicin combined with thalidomide versus doxorubicin alone for patients with unresectable hepatocellular carcinoma

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 27/01/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/07/2009	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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

NTR411; EMC 04-046

Study information

Scientific Title

Acronym
HCC

Study objectives
Previous trials showed that both doxorubicin and thalidomide have anti-tumour activity against hepatocellular carcinoma (HCC). There are indications that these two agents interact synergistically and have non-overlapping toxicity profiles. This trial studies the feasibility and efficacy of doxorubicin combined with thalidomide for the treatment of hepatocellular carcinoma, compared with doxorubicin as single agent.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hepatocellular cancer

Interventions
Control arm: doxorubicin 60 mg/m^2 day 1, three weekly course with in total 6 cycles (maximum 360 mg/m2) given intravenously in 15 minutes.
Experimental arm: doxorubicin treatment as in control arm plus from day 3 on, thalidomide 200 mg daily administered in the evening. When doxorubicin administration has finished, thalidomide should be continued until progression of disease.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Doxorubicin, thalidomide

Primary outcome measure
One-year survival

Secondary outcome measures
1. Response rate scored according to Response Evaluation Criteria in Solid Tumors (RECIST) criteria
2. Time to progression
3. Quality of life
4. Toxicity

Overall study start date
17/06/2004

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Histologically proven HCC
2. Irresectable tumour
3. Failure to previous treatment
4. World Health Organization (WHO) performance status 0 - 2
5. At least 4 weeks since prior treatment with HMG-Coa reductase inhibitors or systemic immunosuppresiva
6. Adequate hepatic and bone marrow function

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30

Key exclusion criteria

1. Prior treatment with doxorubicin or thalidomide
2. Uncontrolled hypertension
3. Unstable angina
4. Arrhythmias requiring treatment
5. Myocardial infarction (MI)
6. Thrombo-embolic events requiring treatment
7. Congestive heart failure or cardiomyopathy requiring treatment
8. Peripheral neuropathy

Date of first enrolment
17/06/2004

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC - Daniel den Hoed
Rotterdam
Netherlands
3075 EA

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
Department of Medical Oncology
P.O. Box 5201
Rotterdam
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Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/content/englishindex.htm

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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