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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

Protocol serial number
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

Study type(s)
Treatment

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(s)
One-year survival

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration