

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 03/07/2009	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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/m² 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 immunosuppressive
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