

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

|                                        |                                                   |                                                      |
|----------------------------------------|---------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>27/01/2006   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>27/01/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                   | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>03/07/2009       | <b>Condition category</b><br>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

Dr S. Sleijfer

### Contact details

Erasmus MC - Daniel den Hoed  
Department of Medical Oncology  
Groene Hilledijk 301  
Rotterdam  
Netherlands  
3075 EA

## 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<sup>2</sup> day 1, three weekly course with in total 6 cycles (maximum 360 mg/m<sup>2</sup>) 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