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Treatment of advanced liver cell cancer with the drug thymostimulin

Submission date 19/12/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/12/2007	**Overall study status** Completed	
Last Edited 30/12/2020	**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

Protocol serial number
N/A

Study information

Scientific Title
Thymostimulin in advanced hepatocellular carcinoma: a phase II trial

Study objectives

To assess efficacy and safety of thymostimulin in the treatment of advanced hepatocellular carcinoma.

Please note that the phase III study of this trial is registered under http://www.controlled-trials.com/ISRCTN64487365.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethik-Kommission of the Medical Faculty of the Martin-Luther-University Halle-Wittenberg (Germany) in May 2000.

Study design
Prospective uncontrolled single-centre phase II treatment study to assess efficacy and safety

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Locally advanced or metastasised hepatocellular carcinoma

Interventions
Thymostimulin 75 mg (Thymophysin CytoChemia® 25/50) subcutaneously for 5 days a week in addition to best supportive care as required.

Patients with tumour regress are allowed non-systemic concomitant treatment with Radiofrequency Thermal Ablation (RFTA) or Transarterial Chemoembolisation (TACE), if the tumour is accessible secondary to the study treatment. In case of tumour progress, patients are allowed to receive salvage therapy.

Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)
Overall survival as well as 1-, 2- and 3-year survival.

Key secondary outcome(s))
1. Tumour response and progression-free survival according to standard World Health Organization (WHO) criteria. Timepoints are:

1.1. Tumour response end of study (three years)
1.2. Overall progression-free survival
2. Toxicity according to Eastern Cooperative Oncology Group (ECOG) criteria

Completion date
31/03/2004

Eligibility

Key inclusion criteria
1. Biopsy- or image-proven locally advanced or metastatic hepatocellular carcinoma not amenable to or failing established treatment
2. Two-dimensional measurable lesion on imaging
3. Life expectancy greater than 3 months
4. Age 18 to 80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
44

Key exclusion criteria
1. Pregnancy/lactation
2. Active second malignancy
3. Severe concomitant disease (e.g. New York Heart Association [NYHA] grade III - IV, serum creatinine level greater than 300 µmol/l)
4. Severe decompensated liver function (bilirubin greater than 5 mg/dl, International normalised ratio [INR] greater than or equal to 2.3)
5. Unable to give informed consent

Date of first enrolment
01/07/2000

Date of final enrolment
30/09/2002

Locations

Countries of recruitment
Germany

Study participating centre
University of Leipzig Hospitals and Clinics
Leipzig
Germany
04103

Sponsor information

Organisation
Martin-Luther-University Halle-Wittenberg (Germany)

ROR
https://ror.org/05gqaka33

Funder(s)

Funder type
University/education

Funder Name
Martin-Luther-University Halle-Wittenberg (Germany) - First Department of Medicine

Results and Publications

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	13/03/2008	30/12/2020	Yes	No