Treatment of advanced liver cell cancer with the drug thymostimulin

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Wolfgang Fleig

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Overall survival as well as 1-, 2- and 3-year survival.

Secondary outcome measures

- 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

Overall study start date

01/07/2000

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

48 participants

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)

Sponsor details

First Department of Medicine Ernst-Grube-Strasse 40 Halle Germany 06114

Sponsor type

University/education

Website

http://www.international.uni-halle.de/

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/03/2008	30/12/2020	Yes	No