ISRCTN64487365 https://doi.org/10.1186/ISRCTN64487365

Treatment of advanced liver cell cancer with the drug thymostimulin in comparison with placebo

Submission date	Recruitment status	[_] Prospectively registered
29/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/06/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/02/2015	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Thymostimulin versus placebo for treatment of advanced hepatocellular carcinoma: a prospective randomised, placebo-controlled, double-blind, multicentre study

Study objectives
To assess efficacy and safety of thymostimulin versus placebo in the treatment of advanced hepatocellular carcinoma.

Study hypothesis: 20% improvement of one-year survival.

Please note that this is the phase III study of a previously registered trial entitled 'Treatment of advanced liver cell cancer with the drug thymostimulin' (see http://www.controlled-trials.com /ISRCTN29319366).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethik-Kommission of the Medical Faculty of the Martin-Luther-University Halle-Wittenberg (Germany), July 2002

Study design
Prospective randomised placebo-controlled double-blind multicentre phase III trial

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 versus placebo (subcutaneous injection) and best supportive care.

Total duration of treatment: maximum of 12 months or until progression; follow-up: 12 months as for treatment; if patient is alive after 12 months, three-monthly follow-up for overall survival.

Intervention Type
Drug

Phase
Phase III

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

Primary outcome measure
Six and 12-month survival.

Secondary outcome measures
1. Overall survival
2. Tumour response and progression-free survival according to standard World Health Organization (WHO) criteria. Timepoints are:
2.1. Tumour response after one year
2.2. Overall progression-free survival
3. Toxicity according to Eastern Cooperative Oncology Group (ECOG) criteria
4. Quality of life assessed by means of the Functional Assessment of Cancer Therapy - Hepatobiliary (FACT-Hep) questionnaire

Timepoints for all primary and secondary outcomes: after 12 months.

Overall study start date
01/10/2002

Completion date
31/03/2006

Eligibility

Key inclusion criteria
1. Biopsy-proven locally advanced or metastasised hepatocellular carcinoma not amenable to or failing established treatment
2. Two-dimensional measurable lesion on imaging
3. Karnofsky score equal or greater than 60%
4. Aged 18 to 80 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
135 participants

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 micromol/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
01/10/2002

Date of final enrolment
31/03/2005

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
06120

Sponsor type

University/education

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

ROR
https://ror.org/05gqaka33

Funder(s)

Funder type
University/education

Funder Name
Cytochemia AG (Germany)

Funder Name
Martin-Luther-University Halle-Wittenberg (Germany)

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	24/08/2010		Yes	No