

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Prospektive, randomisiert, double-blind, placebo-controlled multicenter phase III-study to evaluate the efficacy of octreotide in patients with inoperable hepatocellular carcinoma**

### Trial Acronym

**Hector-Studie**

### URL of the trial

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### Brief Summary in Lay Language

**A preliminary study has shown that the hormone-similar, growth-retarding drug octreotide can prolong survival time in patients with primary liver cancer. Due to methodological deficiencies of the preliminary study the results will be re-checked by the comparison of Octreotid with a pseudo-drug (so-called placebo) primarily regarding to the survival time and secondarily concerning costs, side effects, patient cooperation and quality of life as well as specific conditions in the tumor tissue in both groups with 108 patients with primary liver cancer.**

### Brief Summary in Scientific Language

**A pilot study showed that Octreotid can prolong survival time of patients with HCC. Due to methodological deficiencies the results of this pilot study will be re-evaluated by comparison of Octreotid versus placebo primarily regarding to the global survival time and secondarily concerning the costs, side effects, patient compliance and quality of life as well as the Somatostatin receptors in the tumor tissue and its prognostic relevance in both groups with 108 patients with hepatocellular carcinoma.**

**An interim analysis was done after occurrence of the half of the events (deaths). No significant effect could be shown.**

## Organizational Data

- DRKS-ID: **DRKS00000012**
- Date of Registration in DRKS: **2008/09/05**
- Date of Registration in Partner Registry or other Primary Registry: **2005/09/14**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**

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- (leading) Ethics Committee Nr.: **240/98 , Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

## Secondary IDs

- Primary Registry-ID: **NCT00386984 (ClinicalTrials.gov)**
- Partner Registry-ID: **UKF000513 (Register Klinischer Studien des Universitätsklinikums Freiburg)**

## Health condition or Problem studied

- ICD10: **C22.0 - Malignant neoplasm: Liver cell carcinoma**
- Free text: **Liver Neoplasms**

## Interventions/Observational Groups

- Arm 1: **Somatostatin (octreotide)**
- Arm 2: **pseudo-drug (so called placebo)**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]\***
- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **[---]\***
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]\***

### Primary Outcome

**Overall survival time**

### Secondary Outcome

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### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **1999/10/01**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**Inoperable patients with histologically approved HCC or patients who refuse surgery and who otherwise (e.g. due to the advanced tumor stage) are not applicable for palliative local therapy (e.g. PEI, TACE, RFTA). The inoperability should be approved by an experienced (transplantation) surgeon and documented.**  
**Age: no restriction.**

### Exclusion criteria

#### General

- **Patient with symptomatic Cholecysto-/Choledocholithiasis**
- **Patient with severe psychiatric disease.**
- **Participation in another clinical trial within the last 4 weeks.**
- **Simultaneous participation in another clinical examination.**
- **Legally incapacitated patient, who is not able, to understand nature, meaning and consequence of the study.**
- **Continuous drug or alcohol abuse.**
- **Patient with known HIV infection and antiretrovirale therapy.**
- **Patient with not controllable infection disease.**
- **Pregnancy.**

#### **Study- and indication-specific exclusion criteria**

- **Secondary malignoma without complete remission.**
- **Secondary malignoma with complete remission but current adjuvante therapy.**
- **Preliminary or current therapy with tamoxiphene**
- **Pretreatment of the HCC.**
- **First-time diagnosis > 6 months before inclusion into the study.**
- **Severe hepatic encephalopathy, refractory to any treatment.**
- **Patients with operable HCC.**
- **Contraindication to i.m. injections.**
- **Hypersensitivity to octreotide.**

## **Addresses**

### ■ **Primary Sponsor**

**Gastro-enterologische Abteilung des Universitätsklinikums Freiburg  
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79106 Freiburg  
Germany**

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E-mail: [---]\*

URL: [http://www.uniklinik-freiburg.de/ip/live/index\\_de.html](http://www.uniklinik-freiburg.de/ip/live/index_de.html)

### ■ **Contact for Scientific Queries**

**Evangelisches Diakoniekrankenhaus  
Mr. Prof. Dr. med. Hans-Peter Allgaier  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

## **Sources of Monetary or Material Support**

### ■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

**Novartis Deutschland**

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**Novartis Deutschland**

**Roonstraße 25**

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Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

**Deutsche Krebshilfe e.V.**

**Buschstr. 32**

**53113 Bonn**

**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: **<http://www.krebshilfe.de/kontakt-dkh.html>**

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**Bundesministerium für Bildung und Forschung**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: **<http://www.bmbf.de/index.php>**

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2003/02/28**

## Trial Publications, Results and other documents

- Paper **Allgaier HP, Becker G, Blum HE. [A therapeutic study of hepatocellular carcinoma using octreotide (HECTOR). Hepatocellular Carcinoma: Treatment with Octreotide] Dtsch Med Wochenschr. 2000 Mar 17;125(11):320. German. No abstract available.**

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*\* This entry means the parameter is not applicable or has not been set.*

*\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.*