Purpose

Improvement of the clinical outcome in patients with resectable pancreatic carcinoma through an intensified adjuvant treatment with additional application of cisplatin and regional deep hyperthermia.

Condition
Resected Pancreatic Adenocarcinoma

Intervention
Device: Gemcitabine + Cisplatin + regional hyperthermia
Drug: Gemcitabine

Phase
Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Randomized Two-armed Open Study on the Adjuvant Therapy in Patients With R0/R1 Resected Pancreatic Carcinoma With Gemcitabine Alone (Arm G) vs. Gemcitabine Plus Cisplatin With Regional Hyperthermia (Arm GPH)

Resource links provided by NLM:
MedlinePlus related topics: Fever

Drug Information available for: Cisplatin Gemcitabine Gemcitabine hydrochloride

U.S. FDA Resources

Further study details as provided by Klinikum der Universitaet Muenchen, Grosshadern:

Primary Outcome Measures:
- Disease-free survival (DFS) [ Time Frame: From date of randomization until the date of first documented progression or date of death from any cause, whichever came first, assessed up to 60 months ] [ Designated as safety issue: No ]

Secondary Outcome Measures:
- Overall survival (OS) [ Time Frame: From date of randomization until the date of death from any cause assessed up to 60 months ] [ Designated as safety issue: No ]

Other Outcome Measures:
- Toxicity [ Time Frame: Permanent assessment ] [ Designated as safety issue: Yes ]
- Quality of Life [ Time Frame: Permanent assessment ] [ Designated as safety issue: No ]

EORTC QLQ C30

ClinicalTrials.gov Identifier: NCT01077427
First received: February 25, 2010
Last updated: July 18, 2012
Last verified: July 2012
Estimated Enrollment: 336
Study Start Date: March 2012
Estimated Study Completion Date: March 2017
Estimated Primary Completion Date: March 2015 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</thead>
<tbody>
<tr>
<td>Active Comparator: Gemcitabine</td>
<td>Drug: Gemcitabine&lt;br&gt;Gemcitabine: 1000 mg/m² as iv-infusion on days 1, 8 and 15 of each course (Total dose: 18 g/m²)</td>
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<tr>
<td>Experimental: Gemcitabine + Cisplatin + regional hyperthermia</td>
<td>Device: Gemcitabine + Cisplatin + regional hyperthermia&lt;br&gt;Gemcitabine: 1000 mg/m² as iv-infusion on days 1 and 15 of each course (Total dose: 12 g/m²)&lt;br&gt;Cisplatin: 25 mg/m² as iv-infusion on days 2, 3*, and 16, 17* of each course (Total dose: 600 mg/m²)&lt;br&gt;Regional hyperthermia: 60 minutes on days 2, 3*, and 16, 17* of each course&lt;br&gt;* as an exception for medical or logistic reasons RHT and cisplatin can be applied day 4 instead of 3 and day 18 instead of 17</td>
</tr>
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Eligibility

Ages Eligible for Study: 18 Years to 75 Years (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
1. Any ductal adenocarcinoma of the pancreas confirmed by histology
2. Previous R0 or R1 resection of pancreatic tumor with a standardized procedure
3. No other previous or concomitant treatment of pancreatic carcinoma like radiation, neoadjuvant therapy or immunotherapy
4. No tumor recurrence after surgery
5. Postoperative tumor marker (CEA/CA19-9) ≤ 2.5 x upper limit of normal (ULN) to be documented within 1 week prior to randomization
6. Performance status ECOG 0-2
7. Adequate bone marrow function defined as
   - WBC count ≥ 3.5 x 10⁹/L and
   - platelets ≥ 150 x 10⁹/L and
   - haemoglobin ≥ 9 g/dl documented within 1 week prior to randomization
8. Adequate renal function defined as
   - serum creatinine ≤ 1.2 mg/dL and
   - calculated GFR ≥ 60 mL/min documented within 1 week prior to randomization
9. Adequate coagulatory function defined as
   - Quick-value ≥ 70% and
   - aPTT ≤ 1.5 x ULN documented within 1 week prior to randomization
10. Transaminases (AST, ALT) ≤ 3 x ULN and bilirubin ≤ 2 x ULN documented within 1 week prior to randomization
11. At least 18 years of age
12. Women with childbearing potential and fertile men must use adequate contraceptive measures during and for at least 3 months (female) and 6 months (male) after completion of study therapy (Adequate methods for women are oral contraceptives with estrogen and progesterone, vaginal rings, contraceptive patches, estrogen-free ovulation inhibitors, intrauterine devices with progesterone, 3-month injections with depot progesterone, implants setting free progesterone, abstinence or sterilization (vasectomy) of the male partner. Men must use condoms.)
13. Women with childbearing potential must have a negative pregnancy test within 1 week prior to randomization (postmenopausal women with amenorrhea for more than 1 year are regarded as having no childbearing potential)
14. Written informed consent

Exclusion criteria:
1. Cystic carcinoma of the pancreas
2. Periampullary, papillary cancer
3. Metastatic disease
4. Presence of an active infection grade 3 or higher
5. Other severe disease which could impair the patient's ability to participate in the study according to the investigator's opinion
6. Pregnant or breastfeeding women
7. Known allergies or contraindications with regard to substances or procedures of study therapy
8. Severe, non-healing wounds, ulcers or bone fractures
9. Participation in another clinical trial during this study or within 4 weeks prior to randomization
10. Past or current abuse of illegal or legal drugs or alcohol
11. Other primary malignant diseases in the medical history during the last 5 years (exceptions: carcinoma in situ of the cervix or adequately treated basal cell carcinoma of the skin).
12. Permanent cardiac pacemaker
13. Gross adiposity defined as BMI > 40 kg/m²
14. Treatment with regional hyperthermia not possible for technical reasons (e.g. metal implant)

**Contacts and Locations**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01077427

**Contacts**

Contact: Rolf D. Issels, MD, PhD +49-89-7095-7776 heat@med.uni-muenchen.de

**Locations**

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Principal Investigator: Rolf D. Issels, MD, PhD

**Sponsors and Collaborators**

Klinikum der Universitaet Muenchen, Grosshadern
The European Society for Hyperthermic Oncology
Ludwig-Maximilians - University of Munich

**Investigators**

Principal Investigator: Rolf D. Issels, MD, PhD Klinikum Grosshadern, Medical Center, University of Munich, Germany

**More Information**

Additional Information:

Responsible Party: Rolf D. Issels, PhD, MD, Klinikum der Universitaet Muenchen, Grosshadern
ClinicalTrials.gov Identifier: NCT01077427 History of Changes
Other Study ID Numbers: 115-09 2008-004802-14 AIO-PAK-0111
Study First Received: February 25, 2010
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Health Authority: Germany: Federal Institute for Drugs and Medical Devices

Keywords provided by Klinikum der Universitaet Muenchen, Grosshadern:
pancreatic cancer adjuvant treatment hyperthermia

Additional relevant MeSH terms:

**Fever**
Adenocarcinoma
Carcinoma
Neoplasms, Glandular and Epithelial
Neoplasms by Histologic Type
Neoplasms
Body Temperature Changes
Signs and Symptoms
Gemcitabine
Cisplatin

Antineoplastic Agents
Antimetabolites, Antineoplastic
Antimetabolites
Molecular Mechanisms of Pharmacological Action
Antiviral Agents
Anti-Infective Agents
Enzyme Inhibitors
Immunosuppressive Agents
Immunologic Factors
Physiological Effects of Drugs

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