

2nd-line Treatment in Gemcitabine-Refractory Pancreatic Cancer

REGIONAL HYPERTHERMIA in pancreatic cancer

A phase II trial adding an upper abdominal heating technology (RHT) to gemcitabine and cisplatin as secondline chemotherapy

Trial Title:

Gemcitabine plus cisplatin chemotherapy with the addition of regional hyperthermia as secondline treatment in gemcitabine-refractory patients with locally advanced or metastatic pancreatic cancer

A phase II open clinical trial

EudraCT-Nummer: 2005-003855-11

Trial Design:

For patients with:

Failure after:

- Adjuvant gemcitabine-based treatment
- OR
- 1st-line gemcitabine-based treatment

- Any ductal adenocarcinoma
- Age between 18 and 75
- ECOG 0 - 1

N = 50



**Gemcitabine + Cisplatin
+ RHT**

**Primary Endpoint:
Time to Progression**

- Gemcitabine 1000 mg/m² on day 1, q2w
- Cisplatin 25 mg/m² on days 2 and 4, q2w
- Regional Hyperthermia (RHT): heat (60 min, 42°C) administered to the upper abdominal region (including tumor area, liver) on days 2 and 4, q2w
- Follow up is performed every 6-8 weeks until death or lost to follow-up

Secondary Endpoints:

- Overall survival (OS)
- Clinical response
- Quality of life

For more information, please call the Coordinators Trial Office: +49-89-7095 4768
e-mail to: rolf.issels@med.uni-muenchen.de

Supported by the European Society for Hyperthermic Oncology (ESHO)

