Open for recruitment

HEAT

Hyperthermia European Adjuvant Trial*

A phase III, randomized, open multicenter clinical trial of adjuvant gemcitabine chemotherapy versus intensified therapy with gemcitabine, cisplatin and regional hyperthermia for patients with R0/R1 resected pancreatic cancer

Trial of the: ESHO (European Society for Hyperthermic Oncology)

AIO (Arbeitsgemeinschaft Internistische Onkologie)

For patients with:

Complete (R0) or marginal (R1) resected pancreatic cancer

- **Any ductal adenocarcinoma**
- **Age ≥ 18 years**
- **ECOG 0 - 2**

N = 336

Randomization 1:1

Gemcitabine Standard

Gemcitabine 1000 mg/m^2: days 1, 8 and 15, q4w

Primary Endpoint:

Disease-free Survival

Gemcitabine + Cisplatin + RHT

Gemcitabine 1000 mg/m^2: days 1 and 15, q4w

Cisplatin 25 mg/m^2: days 2, 3* and 16, 17*, q4w

Regional Hyperthermia (RHT) 60 min, 42℃: days 2, 3* and 16, 17*, q4w

* as an exception: for clinical or logistic reasons RHT and cisplatin can be applied day 4 instead of 3 and day 18 instead of 17

Follow up is performed every 3 months until death or lost to follow-up

Secondary Endpoints:

- Comparative overall survival (OS) of patients receiving gemcitabine or gemcitabine + cisplatin + regional hyperthermia
- Comparative DFS and OS of the subgroup of patients receiving at least 4 complete courses of gemcitabine or gemcitabine + cisplatin + regional hyperthermia

For more information, please visit www.pancreas-heat.de or call the HEAT Coordinators Trial Office: +49-89-7095 7776
e-mail to: heat@med.uni-muenchen.de

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