EndoTAG®-1 and Gemcitabine Combination Therapy for the Treatment of Locally Advanced and/or Metastatic Adenocarcinoma of the Pancreas

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/01/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
02/03/2006	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
11/01/2021	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS) 2005-000666-39

ClinicalTrials.gov (NCT)

NCT00377936

Protocol serial number

CT4001

Study information

Scientific Title

EndoTAG®-1 and Gemcitabine Combination Therapy for the Treatment of Locally Advanced and /or Metastatic Adenocarcinoma of the Pancreas

Study objectives

Evaluation of safety and efficacy of the combination treatment versus gemcitabine monotherapy

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Commission II, Faculty for Clinical Medicine Mannheim, Ruprecht-Karls University of Heidelberg, registration number 91/05

Study design

Controlled, randomized, open label, phase II trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Locally advanced and/or metastatic adenocarcinoma of the pancreas

Interventions

Combination therapy of EndoTAG®-1 (lipid-complexed paclitaxel) and gemcitabine with three different doses of EndoTAG®-1 compared to gemcitabine monotherapy

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

EndoTAG®-1 (lipid-complexed paclitaxel Gemcitabine

Primary outcome(s)

- 1. Median overall survival
- 2. Median time to progression

- 3. Response rate
- 4. Clinical benefit
- 5. Adverse events

Key secondary outcome(s))

Not provided at time of registration

Completion date

30/06/2007

Eligibility

Key inclusion criteria

- 1. Inoperable adenocarcinoma of the pancreas
- 2. Histological confirmation
- 3. At least 18 years of age

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

212

Key exclusion criteria

- 1. Any chemotherapeutical treatment for pancreatic adenocarcinoma before enrolment
- 2. Major surgery within four weeks prior to enrolment
- 3. Major cardiovascular disease

Date of first enrolment

26/09/2005

Date of final enrolment

30/06/2007

Locations

Countries of recruitment

Germany

Study participating centre
Universitätsklinikum Mannheim
Mannheim
Germany
68167

Sponsor information

Organisation

MediGene AG (Germany)

ROR

https://ror.org/03kkjyc12

Funder(s)

Funder type

Industry

Funder Name

MediGene AG (Germany)

Results and Publications

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	01/05/2012	11/01/2021	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes