

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

Submission date 19/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/03/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/01/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.medigene.com>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2005-000666-39

IRAS number

ClinicalTrials.gov number

NCT00377936

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

1. Median overall survival
2. Median time to progression
3. Response rate
4. Clinical benefit
5. Adverse events

Secondary outcome measures

Not provided at time of registration

Overall study start date

26/09/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

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)

Sponsor details

Lochhamer Str. 11

Planegg

Germany

82152

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u.schoenherr@medigene.com

Sponsor type

Industry

Website

<http://www.medigene.com>

ROR

<https://ror.org/03kkjyc12>

Funder(s)

Funder type

Industry

Funder Name

MediGene AG (Germany)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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