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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

Registration date
02/03/2006

Overall study status
Completed

Last Edited
11/01/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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
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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