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A prospective, phase III, controlled, multicentre, randomised clinical trial comparing combination gemcitabine and capecitabine therapy with concurent and sequential chemoimmunotherapy using a telomerase vaccine in locally advanced and metastatic pancreatic cancer

Submission date 28/11/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 14/12/2005	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 27/07/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-vaccine-called-gv1001-for-pancreatic-cancer-that-has-spread

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00425360

Study information

Scientific Title
A prospective, phase III, controlled, multicentre, randomised clinical trial comparing combination gemcitabine and capecitabine therapy with concurent and sequential chemoimmunotherapy using a telomerase vaccine in locally advanced and metastatic pancreatic cancer

Acronym
TeloVac

Study objectives
In patients with locally advanced or metastatic pancreatic adenocarcinoma, does the addition of telomerase vaccine GV1001, when given concurrently or sequentially, to combination gemcitabine and capecitabine, improve survival over treatment with combination gemcitabine and capecitabine alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical review pending

Study design
Phase III, prospective, open-label, controlled, multicentre, randomised clinical trial comparing combination gemcitabine and capcitabine with GV1001 in pancreatic cancer with follow-up.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Locally advanced and metastatic pancreatic cancer

Interventions
Arm 1 - Gemcitabine and capecitabine therapy: Gemcitabine will be administered on day one, eight and 15 followed by seven days rest. Per oral capecitabine will be administered morning and evening for 21 days followed by seven days rest. Gemcitabine and capecitabine therapy cycles will be repeated every four weeks until withdrawal from trial treatment.

Arm 2 - Gemcitabine and capecitabine then sequential GV1001 therapy: Patients will receive two cycles of combination gemcitabine and capecitabine before commencing GV1001 alone. Each of the two cycles of combination gemcitabine and capecitabine consists of:
Gemcitabine will be administered on day one, eight and 15 followed by seven days rest. Per oral Capecitabine will be administered morning and evening for 21 days followed by seven days rest. Following completion of gemcitabine and capecitabine therapy, GV1001 will be administered intradermally on Monday, Wednesday and Friday during week eight and once weekly during

weeks nine, ten, 11, 13 and 17. Thereafter, vaccinations will follow a once monthly schedule until withdrawal from trial treatment.

Arm 3 - Concurrent Gemcitabine, Capecitabine and GV1001 therapy: Gemcitabine will be administered on day one, eight and 15 followed by seven days rest. Per oral Capecitabine will be administered morning and evening for 21 days followed by seven days rest. Gemcitabine and Capecitabine therapy cycles will be repeated every four weeks until withdrawal from trial treatment. GV1001 will be administered intradermally on Monday, Wednesday and Friday during week one followed by a once weekly schedule for weeks two, three, four, six and ten. Thereafter, GV1001 will be administered once monthly until withdrawal from trial treatment.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Gemcitabine, capecitabine and telomerase vaccine

Primary outcome(s)
Length of survival

Key secondary outcome(s))
1. Time to Progression
2. Quality of life
3. Clinical Benefit Response
4. Objective response rates according to RECIST criteria
5. Toxicity
6. Survival and response according to Delayed Type Hypersensitivity

Completion date
15/03/2013

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Histologically or cytologically proven pancreatic ductal adenocarcinoma carcinoma
3. Locally advanced or metastatic disease precluding curative surgical resection
4. Contrast enhanced Computed Tomography (CT) scan of the thorax, abdomen and pelvis within 28 days of randomisation
5. Unidimensionally measurable disease (CT) in accordance with the Response Evaluation Criteria in Solid Tumors (RECIST) guidelines
6. World Health Organisation (WHO) performance status zero, one or two
7. Platelets more than 100 x 10^9/l; white blood cell count (WBC) more than 3 x 10^9/l; neutrophils more than 1.5 x 10^9/l at entry
8. Serum bilirubin less than 35 µmol/l
9. Calculated creatinine clearance over 50 ml/min
10. No concurrent uncontrolled medical condition
11. No previous malignant disease other than non-melanotic skin cancer or carcinoma in situ of

the uterine cervix
12. Life expectancy more than three months
13. Adequate contraceptive precautions if relevant
14. Informed written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

Total final enrolment
1062

Key exclusion criteria
1. Medical or psychiatric conditions compromising informed consent
2. Intracerebral metastases or meningeal carcinomatosis
3. Clinically significant serious disease or organ system disease not currently controlled on present therapy
4. Uncontrolled angina pectoris
5. Pregnancy or breast feeding
6. Treatment with chemotherapy, radiotherapy or other investigational drug within the last four weeks prior to inclusion
7. Known malabsorption syndromes
8. Patients with a known hypersensitivity to Fluorouracil (5-FU) or with a Dihydropyrimidine Dehydrogenase (DPD) deficiency
9. Immunosuppressive therapy less than four weeks prior to the start of treatment
10. People of child-bearing potential unless effective methods of contraception are used

Date of first enrolment
01/04/2006

Date of final enrolment
15/03/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Surrey County Hospital
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
The University of Liverpool (UK)

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (C11497/A5690)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014		Yes	No
Plain English results			27/07/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes