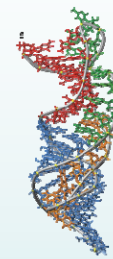


BACKGROUND

Pancreatic cancer is the sixth most common cause of cancer death in the UK
Majority of patients present with advanced disease
GV1001 is a therapeutic telomerase vaccine representing amino acids 611 through 626 of the human telomerase reverse transcriptase catalytic subunit
Phase I/II studies have demonstrated an 8.6 month median survival in pancreatic cancer patients
Increasing evidence that chemotherapy may augment an immune based strategy

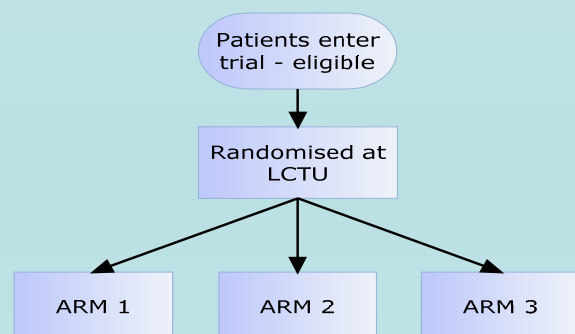


STUDY DESIGN

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

Arm 1: gemcitabine 1000mg/m² given as IV infusion once per week for three weeks followed by one week rest, concurrent with capecitabine 830mg/m² administered orally twice daily for three weeks followed by one week rest (i.e. 4 weeks = 1 cycle)

Arm 2: Two cycles of combination gemcitabine and capecitabine (cycle described previously) before commencing GV1001 alone. GV1001 will be administered on Monday, Wednesday and Friday during week 9 and once weekly during weeks 10, 11, 12 and 14. Vaccinations will then follow a once monthly schedule



Arm 3: Gemcitabine 1000mg/m² given as IV infusion once per week for three weeks followed by one week rest, concurrent with capecitabine 830mg/m² administered orally twice daily for three weeks followed by one week rest (i.e. 4 weeks = 1 cycle) GV1001 will be administered on Monday, Wednesday and Friday during week 1 followed by a once weekly schedule for weeks 2, 3, 4 and 6. Vaccinations will then follow a once monthly schedule

Primary Outcome: Length of Survival

Target recruitment: 1110 patients

SUB-STUDIES

Immunomonitoring: Blood samples taken from consenting Arm 2 and Arm 3 patients to assess whether an immune response to GV1001 can be identified and linked to length of survival

Future Analysis: Blood samples collected from consenting patients in all treatment arms for future genomic and proteomic analysis

SITES OPEN

There are now 51 sites open within the UK.

East Midlands (5)
Eastern region (6)
London (8)
North East (2)
North West (5)
Scotland (2)
South East (9)
South West (11)
Wales (2)
Yorkshire (2)
N Ireland (1)



LATEST FIGURES

854 patients have now been recruited. The top 10 recruiters into this trial are:

Sites Recruiting	Number Recruited
Royal Surrey County Hospital	78
Christie Hospital	53
Royal Liverpool & CCO	54
Weston Park Hospital	45
St Bartholomew's Hospital	41
Guy's & St Thomas Hospital	35
Newcastle General Hospital	36
James Cook, Middlesbrough	27
Royal Marsden Hospital (Surrey)	27
Yeovil District Hospital	25

FOR FURTHER DETAILS PLEASE CONTACT

Dr. Gary Middleton, Chief Investigator
E-mail: Gary.Middleton@royalsurrey.nhs.uk
Tel: 01483 406874

Dr. Christopher Smith, Senior Trial Coordinator
E-mail: Medcks@liverpool.ac.uk
Tel: 0151 794 8898