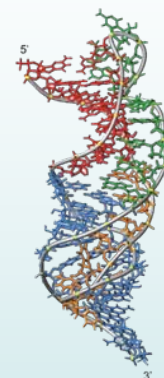




## BACKGROUND

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



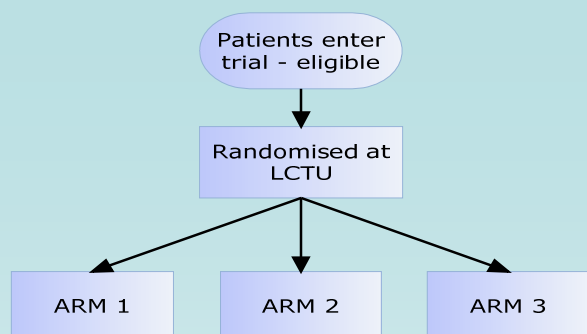
## STUDY DESIGN

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/m<sup>2</sup> given as IV infusion once per week for three weeks followed by one week rest, concurrent with capecitabine 830mg/m<sup>2</sup> 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/m<sup>2</sup> given as IV infusion once per week for three weeks followed by one week rest, concurrent with capecitabine 830mg/m<sup>2</sup> 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



Target recruitment = 1110 patients

## SITES OPEN

There are now 39 sites open within the UK.

- East Midlands (1)
- Eastern Region (4)
- London (7)
- North east (2)
- North West (3)
- Scotland (1)
- South East (7)
- South West (10)
- Wales (2)
- Yorkshire (2)



## LATEST FIGURES

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

- Royal Surrey County Hospital (25)
- Weston Park Hospital (10)
- Clatterbridge Centre for Oncology (9)
- Royal Marsden Hospital (Surrey) (9)
- Guys & St Thomas Hospital (8)
- Salisbury District Hospital (8)
- Royal Liverpool University Hospital (7)
- Southampton University Hospital (7)
- Christie Hospital (6)
- Royal Cornwall Hospital (6)

## FOR FURTHER DETAILS PLEASE CONTACT

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