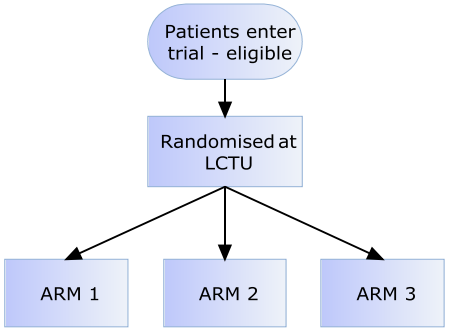
TeloVac Trial

This study is designed as a prospective, phase III, multicentre, randomised clinical trial comparing combination **Gemcitabine** and **Capecitabine** therapy with concurrent and sequential immunotherapy using the **telomerase vaccine (GV 1001)** in locally advanced and metastatic pancreatic cancer.



Patients will be randomised equally between the three arms:

ARM 1 Gemcitabine and Capecitabine

ARM 2 Gemcitabine and Capecitabine then sequential GV1001 followed by further Gemcitabine and Capecitabine for patients where no progressive disease (PD) was demonstrated upon the week 8 CT

ARM 3 Concurrent administration of Gemcitabine and Capecitabine and GV1001

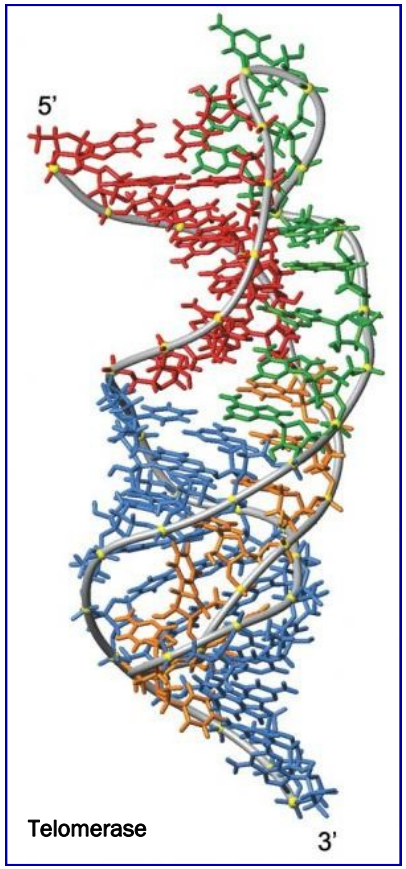
Patients will be stratified by:

- Stage of disease (locally advanced vs. metastatic) and Performance status (0 versus 1 versus 2)

Target recruitment is 1110 patients (370 within each arm).

GV1001 vaccine

Telomerase is a ribonucleoprotein enzyme which is involved in the DNA replication of the cell cycle. The enzyme is over-expressed in majority of human cancers including 90% of advanced pancreatic cancer patients and therefore is a natural therapeutic target in the treatment of cancer.



The over-expression of Telomerase enables the cancer cells to overcome mortality and therefore be a major contributing factor to progression of cancer. Telomerase is one of the body's own proteins and therefore not recognised or attacked by the immune response.

The **GV1001** vaccine targets the over-expressed telomerase by enabling the immune response to recognise the enzyme and illicit an immune response against it. As telomerase is over expressed in majority of cancers and plays a leading role in the mortality of cancer cells, GV1001 could in future become a common cancer vaccine.

Statistical Considerations

Primary outcome measure
= **length of survival.**

One-year survival rate is assumed to be 25% with the aim of improving this in excess of 10%.

Powered to answer two specific hypotheses: does the addition of telomerase vaccine in either experimental arm have a survival benefit over the control arm of Gemcitabine and Capecitabine.

a=0.05 level of significance for the trial as a whole, split equally using a a=0.025 level of significance for each hypothesis.

Recruiting 370 patients (or 280 deaths) into each treatment arm will allow survival differences in excess of 10% to be detected using a 2-sided a=0.025 level of significance (from 25% to 35% with 80% power or from 20% to 30% with 85% power

To Date

40 sites have been given the 'Green Light' and are now open to recruitment.

A further 4 sites have been initiated and around 25 other sites have expressed an interest in taking part in the trial.

There are now several sites taking part in the TeloVac trial in various locations around the UK. Sites are open in the following regions

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

Please visit www.lctu.org.uk for a complete list of sites that are taking part.

Figures updated 08/05/08

The LCTU

The Liverpool Cancer Trials Unit works closely with Cancer Research UK in the clinical research of new and existing products for the treatment of cancer, easing suffering and improving the quality of life for cancer patients.

Further Information

For more information about pancreatic cancer or current trials running within the Liverpool Cancer Trials Unit, please email:

lctu@liverpool.ac.uk

Or visit the LCTU website:

www.lctu.org.uk

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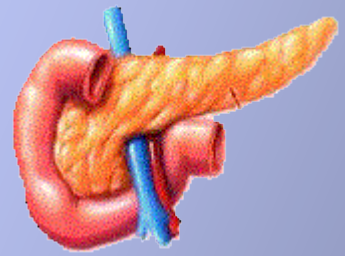
TeloVac



A phase III clinical trial in pancreatic cancer comparing standard therapy with the addition of a telomerase vaccine