

Non-technical Abstract

Complications of cancer, such as weakness, weight loss (cachexia) and anemia are present in more than one half of affected patients. Other clinical manifestations include loss of appetite, muscle wasting, loss of fatty tissue and tiredness resulting in poor quality of life. In addition, cachexia may prevent therapy from being given and may be a direct cause of death. Growth hormone releasing hormone (GHRH) is the natural stimulator of growth hormone and another growth substance called IGF-I. It is possible to treat cancer patients with a DNA-molecule that will code for the natural GHRH. Our hope is that GHRH therapy will stimulate the release of the natural growth factors GH and IGF-I and increase patients' bone and muscle strength. We hope that this treatment will be useful to quality of life and perhaps increase the survival of cancer patients. In this Phase I study we will inject increasing amounts of DNA expressing GHRH, to see how safe this approach is in patients with advanced cancer. We will use a special piece of DNA ("GeneSwitch") that we hope will allow the GHRH gene to be turned on and off by giving a tablet by mouth (mifepristone). We anticipate this will make the treatment even safer.