Cancer Gene Therapy Clinical Trials- Editorial

John Bandelow*

Managing Editor, Journal of Oncology and Cancer Case Reports, Belgium

Corresponding Author*

John Bandelow
Managing Editor,
Journal of Oncology and Cancer Case Reports
Chaussee de la Hulpe 181,
Watermael-Boitsfort, Brussels, Belgium
E-mail: cancercasereports@clinicalres.org

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Perspective

Gene therapy holds promise for treating a wide range of diseases, such as cancer, cystic fibrosis, heart disease, diabetes, hemophilia and AIDS. Researchers are still studying how and when to use gene therapy. Currently, in the United States, gene therapy is available only as part of a clinical trial. Anatomopathological study of the surgical specimen was compatible with Masson's tumor. A 6-months follow-up did not show any recurrence of the lesion. Cancer types, which have been targeted with gene therapy, include brain, lung, breast, pancreatic, liver, colorectal, prostate, bladder, head and neck, skin, ovarian, and renal cancer. Currently, two cancer gene therapy products have received market approval, both of which are in China.

The generation of cancer through a series of changes in the normal cellular genes makes the disease a genetic disease at the cellular base. The involvement of genes in the development of the disease also makes the disease a good candidate for gene therapy.

Gene therapy is not, unfortunately, as simple as injecting genes into the bloodstream. Genes are made of thousands of bases of DNA, and these can't get into cells on its own, so in order to put new pieces of DNA into cells in the body, you need to package that DNA in a virus.

But when CRISPR is used to correct a gene using a strand of DNA that scientists supply to cells, not just to snip out some DNA, it doesn't work very well and unfortunately, most cells in the body liver, neuron, muscle, eye, blood stem cells are not normally dividing. The new guidelines suggest that studies using integrating vectors and genome-editing products follow patients for at least 15 years, while for adeno-associated viral vectors, a minimum 5-year follow-up period is recommended.

Gene therapy has rapidly become one of the most promising new medical developments of our time. It has significant advantages over traditional therapies including the potential for one-time dosage instead of recurring treatment and higher specificity compared to traditional chemotherapy. Cancer is a genetic disease. The one-time gene therapy onasemnogene abeparvovec for spinal muscular atrophy, a rare neuromuscular disorder that is usually fatal by 2 years of age if untreated, has been called the "most expensive drug ever". This flawed characterization raises important methodological.

Clinical trials alone sometimes can take eight years or more. There are many factors that go into that duration including study planning, authorization to run a trial, ethics review, funding, research materials such as patient information, consent forms , and monitoring systems.

Germline gene therapy poses risks not only to patients but also to future generations. Germline gene therapy raises difficult ethical questions related to tampering with human nature, enhancing human traits, parental control over children, discrimination, social justice and eugenics. The idea of germline gene therapy is controversial. While it could spare future generations in a family from having a particular genetic disorder, it might affect the development of a fetus in unexpected ways or have long-term side effects that are not yet known. There are many reasons why a person could be deemed ineligible for gene therapy. Current clinical trials do not include males under 18, women, or those with an active inhibitor. Some trials exclude those who have developed antibodies to the vector used in the gene therapy.

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