

Novel Methods and Compositions for Diagnosing AIDS and Other Diseases Involving Immune System Activation

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Technology description

Summary

Available for licensing and commercial development are methods and compositions suitable for monitoring the progression of AIDS and other diseases whose progression involves immune system activation in mammals, such as cancer, atherosclerosis, Alzheimer's disease, inflammation, autoimmune disorder, allergic asthma, Crohn's disease, Grave's disease, lupus, multiple sclerosis, Parkinson's disease, allograft transplant rejection, and graft vs. host disease.

In particular, the invention relates to the use of the TRAIL (TNF-related apoptosis-inducing ligand) and TRAIL compounds to monitor the progression of AIDS, and such other diseases. This is accomplished by assessing the presence or concentration of TRAIL, especially mTRAIL, sTRAIL, the TRAIL DR5 receptor molecule, and biological molecules that activate TRAIL or its receptor. These biological molecules include p53, alpha- and beta-interferon, as well as additional compounds such as CD69 and HLA-DR. Also claimed are kits for immunoassays to determine the presence or concentration of a TRAIL compound in a biological fluid, suitable for determining whether the mammal suffers from any of the above diseases.

TRAIL can be used as a new surrogate biomarker to monitor the progression of HIV infection and other conditions and diseases associated with immune system activation. In the case of HIV infection, measuring levels of this biomarker can distinguish among infected individuals with high viral load, infected individuals with low viral load, and uninfected individuals. Only two surrogate markers are currently recognized by the Food and Drug Administration as clinically relevant to HIV progression, HIV viral load and the absolute number of peripheral CD4+ T cells. Tests for assessing HIV viral load employ PCR, the use of which has drawbacks, including cross-contamination. TRAIL has mechanistic implications for HIV-1 pathogenesis and directly correlates to viral load but not necessarily inversely with CD4+ T cell count. Other surrogate markers have been proposed but do not consistently reflect AIDS progression in all individuals or may result in overlooking possible treatments that may affect disease progression but do not affect the chosen marker. Therefore, use of this new biomarker to assess disease progression in infected individuals and to evaluate the effectiveness of various treatment regimens has several advantages over currently used methods, since TRAIL is a death molecule

involved in CD4+ T cell depletion in HIV/AIDS. TRAIL, its receptor, and activating molecules can all be used as sensitive markers for CD4 T cell activation and apoptosis.

Institution

[NIH - National Institutes of Health](#)

联系我们



叶先生

电 话 : 021-65679356

手 机 : 13414935137

邮 箱 : yeyingsheng@zf-ym.com