



Trial name. **LIGHTHOUSE TRIAL**

Human endogenous retrovirus K (HERV-K) can be found in motor neurones in the brain (E) and spinal cord (F) from people who died from MND.

A BRIEF HISTORY OF THE RESEARCH

Despite decades of research, the cause and treatment of MND remains unknown. One of the most interesting theories is that MND may be caused or triggered by a type of virus called human endogenous retrovirus (HERVs). These viruses infected animals and humans during millions of years of evolution and over time they became part of our genetic makeup (genes). Approximately 8% of human genes have retroviral origins. These HERVs were only discovered around 20 years ago and it is still unknown exactly how they may be related to causing human diseases. However, there is very good evidence that in animals these viruses are associated with a number of neurological conditions. Some preliminary research suggests that one particular retrovirus called HERV K may be linked to MND.

Reviews by Alfahad and Nath (Alfahad T, Nath A. Retroviruses and amyotrophic lateral sclerosis. Antiviral Res. 2013,99(2).180-187) Ave documented the extensive research on reverse transcriptase activity in MND. In early 2016 scientists at the NIH showed that brain samples from MND patients had higher than normal levels of messenger RNA (mRNA) encoded by genes of the human endogenous retrovirus K (HERV-K). A protein encoded by a critical HERV-K gene, called env, was found in brain samples from MND patients but not from healthy individuals. They also showed that activation of HERV-K genes killed healthy human neurons grown in petri dishes. To test the role of HERVs in MND, the scientists genetically modified mice so that their neurons activated the HERV-K env gene. The mice died earlier than normal and had problems with balance and walking that progressively worsened with age, showing similar symptoms to human MND. When the scientists inspected the brains, spinal cords and muscles of these mice they found that only motor neurons, the cells that control movements and die in MND, were damaged. Cells in other parts of the nervous system remained healthy.

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MOVING FROM THE LABORATORY INTO THE CLINIC

The Lighthouse Trial was the first clinical trial in the world conducted with modern combination antiretroviral therapy to ameliorate disease progression in patients with MND/ALS.

The study is now complete and showed that the drug from this trial, Triumeq, could be safely administered to MND patients. Next, researchers are hoping to perform a larger Phase 2 study to determine if Triumeq can slow or halt the progression of MND.

Detailed inclusion criteria and further information about this trial is available by clicking on the following link https.//clinicaltrials.gov/ct2/show/ NCT02868580

Please note: FightMND plays no part in determining eligibility criteria of the trials it funds. Please consult with your MND specialist to assess your suitability for trial inclusion.