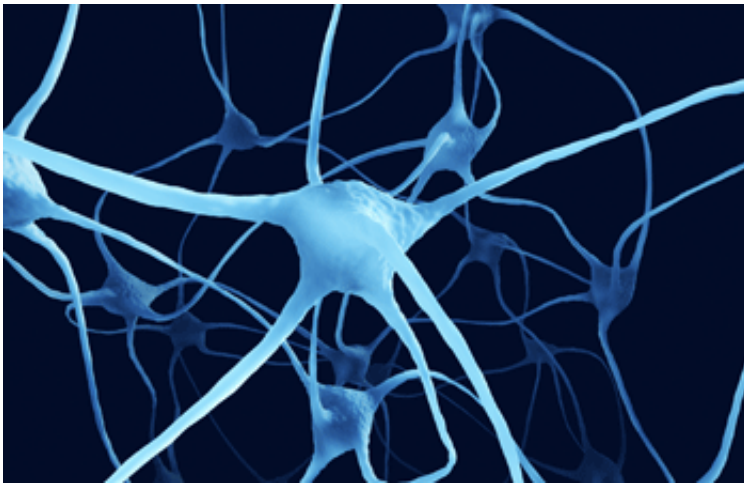


# UK study finds diaphragm pacing not beneficial to MND patients

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A pioneering trial investigating the safety and efficacy of diaphragm pacing used to alleviate breathing difficulties for people with motor neurone disease (MND), has revealed the intervention is not generally beneficial to patients.

A team of MND specialists, led by researchers from the Sheffield Institute of Translational Neuroscience (SITraN), conducted the first randomised controlled multi-centre clinical trial to assess the risks and benefits of the intervention for patients.

The diaphragm pacing device was approved for humanitarian use in

MND patients in 2011 by the US Food and Drug Administration.

Despite a lack of conclusive evidence for the benefits of the intervention, diaphragm pacing is now widely offered to patients with MND around the world.

The device, which is similar to a heart pacemaker, sends electrical impulses to stimulate the main breathing muscles in the diaphragm.

The results of the Protocol for diaphragm pacing in patients with respiratory muscle weakness due to [motor neurone disease](#) (DiPALS) study, published in the journal *Lancet Neurology*, show that diaphragm pacing was not beneficial when used in addition to non-invasive ventilation (NIV) where slightly pressurised air is delivered into the lungs through a face mask. In fact, patients who used diaphragm pacing lived on average 11 months less than those who used NIV alone.

Lead researcher, Dr Christopher McDermott from SITraN, who is based at the University of Sheffield, said: "The results from the DiPALS study are incredibly disappointing, because as a researcher and an MND doctor you start out with some hope that this is a treatment that can be truly beneficial for people living with MND.

"Unfortunately, DiPALS did not show any benefits for diaphragm pacing in MND and, in fact, our study showed that it may actually be harmful. Although the results are disappointing, it was an important study to carry out as this evidence shows us that for most people there is no benefit in having diaphragm pacing and that the major surgery needed is something people living with MND should not go through."

He added: "We carried out the DiPALS study because [breathing difficulties](#) are a major problem in MND, especially during the later stages of the disease. Current guidelines recommend non-invasive

ventilation (NIV) should breathing difficulties arise, however we know that the benefits of NIV are limited and that NIV does not suit everyone. Therefore, research into complementary and alternative techniques to help with breathing is needed.

"We were aware of the work in the United States on diaphragm pacing in MND and we wanted to know if it would be beneficial for our patients. Therefore, we decided to design a randomised controlled clinical trial of diaphragm pacing in MND.

"Funding bodies like the NHS and NICE need this evidence of benefit before a treatment can be made available in the UK. Also, because it is a treatment that requires a major operation, we wanted to make sure beyond reasonable doubt that diaphragm pacing is worthwhile for patients, adding sufficient benefit such as living longer and a better quality of life.

"We established collaboration within the MND community, including the Dementia and Neurodegenerative Disease Research Network (DeNDRoN) and the MND Association and we then applied for funding from the National Institute for Health Research (NIHR) to carry out this clinical trial. By collaborating with other UK MND Care Centres we were able to carry out a well-designed clinical trial to determine if this intervention was beneficial to people living with MND."

Dr McDermott concluded: "MND is an awful disease and affected individuals, loved ones and the health care professionals involved in providing care, are understandably always eager to consider new treatments. It is important that new treatments are evaluated in rigorous trials to demonstrate their benefit and importantly ensure no harm is done. The result from DiPALS demonstrates that the increasing 'nothing to lose' approach is inappropriate and we should not lower our standards by starting treatments without clear evidence of benefit.

"I am always humbled by the precious time and effort individuals give up to take part in our research studies. Those individuals who participated in DiPALS have contributed enormously to ensuring we understand the effects of diaphragm pacing in patients with MND and will ensure that we now put our focus and resources into developing other treatments that may help."

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