

Hand-held device may prevent migraine

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Neuralieve Clinical Trial TMS Device

(PhysOrg.com) -- A new portable device that delivers a magnetic pulse to the back of the head could prevent or treat migraines in people susceptible to them.

The device was developed at the Montefiore Headache Center attached to the Albert Einstein College of Medicine in the Bronx, New York. Just over two hundred patients from 16 medical centers across the US took part in the three-month trial, with half given a placebo device that looked identical to the real gadget. The patients reported having from one to eight migraines with aura each month before the trial. The patients were told to give themselves two pulses to the back of their heads when they experienced early symptoms of a migraine, and to record their pain levels immediately after the pulses, after 30 minutes, and then again after one, two, 24, and 48 hours.



The device is hand-held, and emits a single pulse trans-cranial <u>magnetic</u> <u>stimulation</u> (sTMS). The pulse is believed to disrupt the <u>electrical</u> <u>activity</u> in the brain that causes early symptoms of migraines producing auras — visual disturbances such as zigzags, spots of light or blind spots, or sensory disturbances such as numbness or tingling. There may also be nausea, and visual or auditory hallucinations.

The results of the trials found it kept 39% per cent of patients using the real device pain free for two hours after using the gadget, and some reported remaining pain free for up to 48 hours. Of the placebo group 22% reported being pain free for two hours afterwards. There was no significant difference in the severity of aura symptoms between the test and placebo groups.

Patients reported the device was easy to use, and researchers found no serious side-effects. The device is small enough to be used at home, unlike previous devices, which were large and expensive, and suitable only for use in a clinic.

Dr Richard B. Lipton, director of the Montefiore <u>Headache</u> Center, said there was a significant unmet medical need in migraine treatment. Some people do not tolerate the drugs well, while others would prefer a drugfree treatment method.

Around 20-30% of migraine sufferers experience aura symptoms, but drugs used to treat migraines and severe headaches are not effective in the aura stage early in a migraine episode. The new device is used in the aura phase, and may reduce or eliminate the need for drugs.

More research is needed to calculate the timing between doses of the magnetic pulses. The results of the trial will be published in the March issue of *The Lancet Neurology*. The research was funded by Neurolieve, a Californian medical technology company that hopes to market the



device if it receives FDA approval.

More information: Richard B Lipton et al., *The Lancet Neurology*, Early Online Publication, 4 March 2010; doi:10.1016/S1474-4422(10)70054-5. <u>www.thelancet.com/journals/lan</u> ...(10)70054-5/abstract

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