



## **Research project:**

### **Non-invasive transcranial cerebellar stimulation: double blind, randomised, sham-controlled study followed by an open label extension phase**

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## **Scientific Summary**

Cerebellar transcranial Direct Current Stimulation (tDCS) is a non-invasive treatment which has been demonstrated to modulate cerebellar excitability and improve motor symptoms in patients with neurodegenerative cerebellar ataxias. In a previous study, this group showed that two weeks of tDCS improved symptoms, and this improvement could be seen for up to three months. These researchers now aim to study whether repeating anodal cerebellar tDCS for two weeks, after a three month interval, may prolong clinical improvement, and whether tDCS intervention might improve cerebellar cognitive-affective syndrome (CCAS; Schmahmann's syndrome).

They will perform a double blind, randomised, placebo-controlled study with cerebellar tDCS (5 days/week for 2 weeks; anodal tDCS:placebo tDCS=1:1) in patients with Friedreich's ataxia (FA), spinocerebellar ataxia (SCA), or multiple system atrophy (MSA). Each patient will undergo a clinical evaluation, and cerebellar brain inhibition (CBI) connectivity assessment by Transcranial Magnetic Stimulation at baseline (T0), after tDCS treatment (T1), and at 3-months follow-up (T2). An open-label phase will follow, in which all included patients will receive anodal cerebellar tDCS stimulation (5 days/week for 2 weeks), and will undergo the same standardised assessment after treatment (T3), at 3-months follow-up (T4), at 6-months follow-up (T5), and at 12-months follow up (T6).

They will consider clinical scales as primary outcome measures, and CBI assessment as secondary outcome measures. If the results are positive, tDCS would be envisioned as a promising rehabilitating approach in neurodegenerative ataxias.

## **Lay Summary**

No treatment is available for most ataxias, but recent studies have reported that applying a low electrical current to the scalp may alleviate symptoms. This technique is known as cerebellar transcranial Direct Current Stimulation (tDCS). tDCS is a portable, painless, non-invasive and easy-to-perform technique, which induces activity in the brain. Repetitive stimulations, for example on a daily basis for two weeks, can induce long-lasting effects.

These researchers have recently conducted a small pilot study in people with neurodegenerative ataxia to evaluate the potential benefit of tDCS in ameliorating symptoms, with very promising results. They delivered tDCS to the cerebellum and the spinal cord for two weeks in a double-blind study (ie some patients received real tDCS, some patients received placebo tDCS with the device switched off, in a randomised order). The people that received real tDCS showed a significant improvement in cerebellar symptoms and quality of life compared to those who received placebo tDCS. After two weeks of tDCS treatment, this improvement could be detected for up to three months.

The goal of the present study is to confirm and extend these preliminary findings, by including a larger number of patients, and repeating the treatment after a three month break.

People with Friedreich's ataxia (FA), spinocerebellar ataxia (SCA), or multiple system atrophy (MSA) will undergo two weeks of treatment with cerebellar/spinal cord tDCS (real treatment) versus placebo treatment. The effects of tDCS will be assessed for three months. After three months, all subjects will undergo an additional two weeks of treatment with real tDCS, and effects will be further assessed for another three months.

This project might open a new avenue of therapeutic care for those with neurodegenerative ataxia, and show whether multiple tDCS sessions are able to delay progression of ataxia.

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