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CLINICAL EVIDENCE BRIEFF:

Effectiveness and Safety of Purified Cannabidiol (100 mg BID) for Central Neuropathic Pain in Multiple Sclerosis and Neuromyelitis Optica Spectrum Disorder: Preliminary Findings from a Multicenter Pilot Study

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The European Charcot Foundation is an independent and non-profit organization dedicated to the advancement of MS research and its annual congress is the most prestigious in terms of its scientific content bringing together leading experts, researchers and clinicians to discuss the most promising innovations that are shaping the future of MS management, TENMO and MOGAD.

These preliminary findings on cannabidiol (CBD) validate its consideration as an emerging therapy of interest to address a debilitating symptom, often refractory, in complex populations and with unmet therapeutic needs.

- Multicenter prospective study (EMCA) evaluating Convupidiol® for moderate-to-severe Central Neuropathic Pain (CNP) associated with Multiple Sclerosis (MS) and Neuromyelitis Optica Spectrum Disorder (NMOSD), conditions frequently refractory to conventional analgesic therapies.

- Oral solution of Convupidiol® administered at **100 mg twice daily** (total daily dose: 200 mg/day) over 12 weeks, as the sole targeted pharmacological intervention for CNP during the study period.

- Interim analysis of the initial cohort (n=8) demonstrated a **consistent reduction trend across all Numeric Rating Scale (NRS) pain scores** (maximum, minimum, average, and current pain) from baseline to week 12.

- **Consistent improvements in Health-Related Quality of Life** (HRQoL, assessed via MSQOL-54), particularly regarding pain interference with daily activities, mood, and ambulation.

- **A marked reduction** in the requirement for rescue analgesic medication was observed at week 12.

- **Purified CBD was well tolerated, with no Serious Adverse Events (SAEs)** reported during the interim evaluation.

- Findings warrant cautious interpretation due to the open-label, **uncontrolled design and preliminary sample size (n=8).**

- Preliminary findings suggest that **Convupidiol® (200 mg/day) may alleviate CNP intensity and reduce its functional impact in MS and NMOSD patients**, supporting ongoing cohort completion and full analysis.

Effectiveness and Safety of Cannabidiol (100 mg Twice Daily) for Central Neuropathic Pain in Multiple Sclerosis and Neuromyelitis Optica Spectrum Disorder: Preliminary Findings from a Multicentre Pilot Study

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BACKGROUND

Central neuropathic pain (CNP) is a prevalent and frequently debilitating symptom in individuals with multiple sclerosis (MS) and neuromyelitis optica spectrum disorder (NMOSD), often resistant to conventional analgesic therapies. Cannabidiol (CBD), a non-psychoactive phytocannabinoid, has shown potential therapeutic effects, including analgesia. Robust clinical evidence supporting its specific use for CNP in MS and NMOSD, especially with standardised oral formulations and dosages, was limited when the study began. This represents the first available information for this CBD formulation in this population, which is a strength of the study.

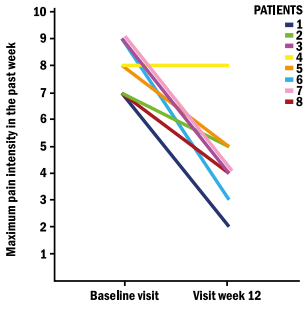
OBJECTIVES

To prospectively assess the preliminary effectiveness and safety of oral cannabidiol solution (100 mg twice daily) over 12 weeks in patients with MS or NMOSD experiencing moderate to severe CNP, following the clinical decision to initiate CBD in a real-world practice setting. Primary outcomes included changes in pain intensity (Numeric Rating Scale, NRS) and health-related quality of life (Multiple Sclerosis Quality of Life-54, MSQOL-54).

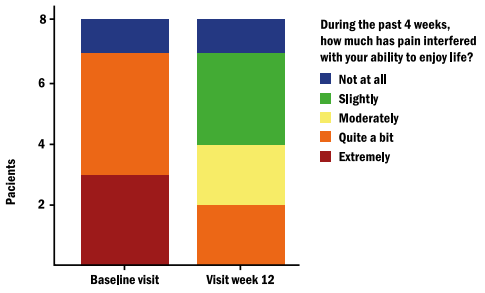
METHODS

The EMCA study is an ongoing, multicentre, prospective investigation. Eligible participants were adults (18–70 years) with a confirmed diagnosis of MS or NMOSD for at least one year, suffering from moderate to severe CNP (as per NRS scores) despite stable baseline analgesic regimens for > 6 months. During the 12 weeks of evaluation, CBD (100 mg twice daily) was the only pharmacological intervention specifically assessed for central neuropathic pain. Pain intensity (NRS: maximum, minimum, average over the past week, and current pain) and MSQOL-54 were assessed at baseline and week 12.
This is an interim analysis. Of 16 patients enrolled to date, this summary presents preliminary findings from the first 8 patients who completed the 12-week follow-up. The remaining 8 patients are still active and in follow-up in the study.

Assessment of maximum pain during the last week at the baseline visit and after receiving CBD 200 mg per day for 12 weeks. At week 12. n=8



Assessment by MSQUOL 54 at the baseline visit and after administration of CBD 200 mg per day for 12 weeks. At week 12. n=8



PRELIMINARY RESULTS

The initial cohort of 16 enrolled patients was predominantly female (81.3%, 13/16). Baseline characteristics of the 8 patients who completed 12-week follow-up include a median EDSS of 2 (IQR 0-3.2), a median disease duration of 5.5 years (IQR 2-11.5), a median number of relapses of 1.5 (IQR 1-2.75), and 75% (6/8) of patients receiving biologic treatment. The phenotype distribution was as follows: Relapsing-Remitting MS (RRMS) 50% (4/8), Secondary Progressive MS (SPMS) 12.5% (1/8), NMOSD AQP4+ 25% (2/8), and NMOSD AQP4- 12.5% (1/8).
Preliminary analysis indicated a trend towards reduced NRS pain scores (maximum, minimum, average, and current) from baseline to week 12 in most patients, as seen in the individual bar charts. Improvements were also observed in pain interference with general activity, mood, walking ability, and enjoyment of life at week 12 compared to baseline (MSQOL-54 data). There was a reduction in the need for rescue analgesia between baseline (50% [8/16] of the enrolled cohort required rescue) and week 12 (25% [2/8] of the evaluated patients required rescue at that time point).
CBD treatment was generally well tolerated. Mild headache, possibly related to CBD, was reported at week 4 and resolved spontaneously. No serious adverse events were reported during this preliminary phase in this 8-patient cohort.

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CONCLUSION

These preliminary findings suggest that cannabidiol therapy at 100 mg twice daily may be associated with improvements in CNP intensity and its impact on daily function and quality of life in patients with MS and NMOSD in a clinical practice setting. The observed safety profile in this small initial cohort appears favourable. These results should be interpreted with caution due to the effectiveness study design (open-label, non-controlled), the small sample size, and the preliminary nature of the data. It is important to note that as an interim analysis of the first 8 'completers', a potential selection bias exists, as these patients who completed follow-up first may not be representative of the total cohort of 16 patients once all have completed the study. Completion of the ongoing EMCA study and full cohort analysis will be essential to validate these initial observations

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