Introduction. Migraine is a multifactorial pathology that affects 12 percent of the world’s population. Relivion® MG (Neurilief Inc., USA) is a non-invasive self-administered device for external combined occipital and trigeminal nerve stimulation that has been recently approved for marketing in Europe and the USA. The objective of this study was to conduct an early assessment of the efficacy and safety of Relivion for the treatment of migraine episodes.

Methods. Relivion was identified by the early awareness and alert system, SINTESIS- nuevas tecnologías, of the Agencia de Evaluación de Tecnologías Sanitarias at the Instituto de Salud Carlos III. An early assessment of the technology was conducted by reviewing relevant clinical studies published to 29 September 2021. The literature was identified by searching PubMed, Embase, the International Clinical Trials Registry Platform, ClinicalTrials.gov, and the Cochrane Library.

Results. Two randomized, sham-controlled double-blind trials were found. They assessed side effects and pain relief, response rate, and pain freedom two hours after treatment. One study included 55 patients and the other (the RIME study) included 131 patients. The rate of pain relief two hours after treatment ranged from 60 to 76 percent in the treatment group and from 31 to 37 percent in the control group (p<0.01). The response rate, defined as at least 50 percent pain reduction two hours after treatment, was significantly higher in the treatment group (67 to 70% versus 32 to 42%). The percentage of patients free of pain two hours after treatment ranged from 42 to 46 percent in the treatment group, compared with 11 to 12 percent in the control group (p<0.0001). No notable adverse events were recorded.

Conclusions. Preliminary results indicated that Relivion effectively and safely relieves or eliminates acute migraine pain. However, more comparative studies are needed. The use of Relivion could improve the control of symptoms and improve quality of life in patients with migraine.