

# Botulinum toxin in the treatment of chronic migraine

Although largely unknown to the general population, Botulinum Toxin type A is officially accepted for the treatment of chronic migraine.

**B**otulinum Toxin is a neurotoxin produced by the bacterium *Clostridium Botulinum*. There are several subtypes of Botulinum Toxin, but it is subtype A that is used in the treatment of chronic migraine. This treatment has been approved by the FDA (Food and Drug Administration) since October 2010 and more recently also by the European Headache Federation. This approval was based on study Phase III Research Evaluating Migraine Prophylaxis Therapy (PREEMPT) 1 and 2, in which there was a significant reduction (more than 50%) in the number of days and migraine episodes. The PREEMPT Botulinum Toxin A administration protocol, is used in most chronic migraine treatment centers and has a responder rate of 2/3.

The pathophysiological mechanisms underlying chronic migraine have not yet been fully understood,

however, it appears that atypical pain processing, central and peripheral sensitization, cortical hyperexcitability and neurogenic inflammation play an important role.

Botulinum toxin, besides its well-known effect on the motor plaque, also acts on the sensory afferent nerve terminals (C fibers), inhibiting the release of local inflammatory substances.

All patients with chronic migraine are considered eligible for treatment with Botulinum Toxin A. Chronic migraine is defined as headaches that occur for 15 days or more during in a month over a 3-month period with migraine type pain on at least 8 of those days. It is estimated that 1 to 2% of the population suffer from migraines and it is estimated that one-third of patients are not treated adequately.

The application of Botulinum Toxin A is carried out according to a pre-established protocol, which was approved according to previous

clinical trials. According to the PREEMPT study, the protocol involves injecting in 31 pre-defined spots situated between the cephalic and cervical regions. A very thin and small needle is used minimizing the pain caused by the injection. A brief local burning sensation may be felt. The procedure is usually well tolerated by patients who can resume their usual activities immediately. This procedure should be performed only in centers with experience in this protocol and the same implies to the clinical correlation and vigilance in the Headache Consultation.

The practical effect of Botulinum Toxin A, is not immediate and in order to evaluate the treatment's positive response, at least 2-3 applications are required. The treatment is carried out with 12-week intervals. If no improvement is observed this treatment is suspended. If improvement is observed treatment can be extended for as long as necessary. Current clinical trials suggest that some patients taking Botulinum Toxin A, improve to the point that treatment can be discontinued and no further migraine experienced.



According to current studies, there are no serious adverse effects in patients treated with Botulinum Toxin. Although the treatment is considered to be very safe, just as with all other medication it is not free of adverse effects. Cervical pain and stiffness may occur, especially on the spots where the medication was applied; in this case the effect is transient and disappears in days or weeks. Anti-inflammatory medication can be taken, avoiding muscle relaxants. Other less frequent side effects are temporary drooping eyelids and very rarely influenza-like symptoms. All these adverse effects are considered transient and disappear in days or

weeks. Contraindications apply for patient with known hypersensitivity to any preparation of Botulinum Toxin or with known pre-existence neuromuscular junction dysfunction, e.g. Myasthenia Gravis, patients with known prior autonomic dysfunction. There are no safety studies during pregnancy therefore this treatment is not recommended for pregnant women.

The Out-Patients Consultation on Headaches and the Out-Patients Consultation on Botulinum Toxin are performed by Dr. Leandro Valdemar Specialist Neurology and Neurophysiology.



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