

Migraine Fact Sheets

Botox for Migraine

Introduction - Botulinum toxin (Botox®) for chronic migraine

Botox® (onabotulinum toxin A) was licensed specifically for the treatment of chronic migraine in July 2010 by the Medicines and Healthcare products Regulatory Agency (MHRA). Botox® has not been shown to be effective for any other headache type (e.g. episodic migraine, tension-type headache, cluster headache) as yet. This fact sheet outlines the evidence for the use of botulinum toxin in headache.

What is botulinum toxin?

Botulism – paralysis of muscles caused by high doses of botulinum toxin – was first described in 1817. The responsible bacterium, *Clostridium botulinum*, was not isolated until 1895. Seven different subtypes of botulinum toxin (A-G) are known. A highly dilute preparation of botulinum toxin type A (Botox®) was introduced in clinical practice in the 1970s and 1980s to treat squint and blepharospasm. Since then it has found uses in other areas of medicine including dystonia (including writer’s cramp), post-stroke spasticity, and hyperhidrosis. Other botulinum toxin preparations are available, both of type A (Dysport and Xeomin) and type B (Neurobloc or Myobloc), but these have never been tested in headache disorders.

Botulinum toxin and headache

In the mid-1990s a number of people reported improvement in headaches in patients receiving botulinum toxin for other reasons. Well-conducted clinical trials of botulinum toxin in various types of headache followed, but the results were disappointing, with no difference over placebo being found in tension-type headache, episodic migraine, and undifferentiated chronic headache. Detailed analysis of the results suggested, however, that there might be a subgroup of patients with chronic migraine who could benefit, and further trials were undertaken.

Botox® in chronic migraine: the PREEMPT trials

Two Phase 3 Research Evaluating Migraine Prophylaxis Therapy (PREEMPT) trials recruited 1384 patients with chronic migraine, and randomised them to treatment with Botox® or placebo. These patients were suffering on average 20 days of headache each month, of which 18 were moderate or severe. Those randomised to Botox® received fixed-site, fixed dose injections every 12 weeks over 56 weeks. These injections covered seven specific areas of the head and neck, with a total dose of between 155-195 units. At six months, after two cycles of treatment, those treated with Botox® had on average eight less days of headache each month. After 12 months, 70% of those treated had $\leq 50\%$ the number of headaches that they had done originally. Botox® was well-tolerated, the commonest side effects being neck pain (6.7%), muscular weakness (5.5%), and drooping of the eyelid (3.3%). No serious irreversible side effects have ever been reported in trials of Botox® in headache.

How does botulinum toxin work in chronic migraine?

The simple answer is that we don't know – yet. Unlike many of the other conditions in which it is used, it is not thought to work by relaxing overactive muscles. Botulinum toxin has been shown to reduce pain in a number of disease states, including cervical dystonia, neuropathic pain, lower back pain, spasticity, myofascial pain, and bladder pain. Botulinum toxin is believed to inhibit the release of peripheral nociceptive neurotransmitters, which may then have a knock-on effect on the central pain processing systems that generate migraine headaches.

Is Botox® right for me?

Only patients with chronic migraine are eligible for treatment with Botox®. Chronic migraine is defined as headaches occurring on 15 or more days each month, at least half of which have migrainous features. There are, however, other treatments available to patients with chronic migraine, and it is important that patients have an informed discussion of their headaches and the options for treatment with a practitioner experienced in the diagnosis and management of headaches before a decision to use Botox® is taken.

Who can inject Botox® for chronic migraine?

At present the use of Botox® is restricted to a few specialist headache centres, but as time goes on there should be increasing numbers of trained injectors available. In all cases, however, you should ensure that the person injecting has received appropriate training, both in the diagnosis and management of chronic migraine, and in the delivery of Botox® according to the proven PREEMPT schedule.

Please note that the referral process differs for each location. In the first instance, patients who are struggling to manage their symptoms should discuss this with their general practitioner (GP) and if appropriate, seek referral to a specialist with an interest in headache disorders. For further information please refer to The Migraine Trust's fact sheet [Migraine Clinics](#).

On visiting a migraine clinic a detailed history of the patient's condition will be taken, including symptoms, frequency of attacks and any medication tried in the past or currently taking. Keeping a diary can help with this - see The Migraine Trust's fact sheet [Migraine Diaries](#).

Availability of Botox® for treating chronic migraine on the NHS

The National Institute for Health and Clinical Excellence (NICE) issued [guidance](#) in June 2012 recommending Botox® is made available on the NHS as a preventive treatment option for adult patients with chronic migraine - this applies to NHS settings in England and Wales.

The Scottish Medicines Consortium (SMC) has advised NHS Scotland not to offer Botox® for the prophylaxis of headaches in adults with chronic migraine ([2011](#) and reviewed in [2013](#) following resubmission). This [guidance](#) may be reviewed in future.

Following the NICE guidance, local NHS healthcare providers in England and Wales had three months to ensure the funding and resources were in place for suitable patients to access

the treatment following recommendation by a suitably qualified health professional. This time frame has now elapsed (as of October 2012) and the treatment should be available locally on the NHS for those meeting the [criteria](#). Access to treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you, is a patient right enshrined in the [NHS Constitution](#).

If your health professional has recommended that you are suitable for this treatment, but you or your health professional are having difficulty accessing the funding or resources for you to receive Botox® from your local NHS healthcare provider, then The Migraine Trust's [Advocacy Service](#) may be able to provide further support. You may also find it helpful to read our [Patient Advocacy Toolkit](#).