Botulinum toxin Type A was recommended by the National Institute for Health and Care Excellence (NICE) in June 2012 for the prevention of headaches in selected adults with chronic migraine.

What is Botulinum toxin?
The toxin is a protein and is produced by a bacterium called Clostridium Botulinum. Botulinum toxin was first introduced in medical practice in the 1970s to treat squint and other eye disorders. Since then it has found uses in other areas of medicine and more recently in the treatment of chronic migraine. Only very small doses, enough to weaken but not paralyse muscles, are used medically. High doses of botulinum toxin are known to cause paralysis of muscles.

What is the evidence that Botulinum toxin can help chronic migraine?
Two large research trials (PREEMPT) recruited 1384 patients with chronic migraine. These patients were randomized and treated with Botulinum toxin or placebo. These patients were suffering on average 20 days of headache each month, of which 18 were moderate or severe. Those randomized to Botulinum toxin received 31 injections into specific sites in the head and neck every 12 weeks over a year. After 12 months, 70% of those treated with Botulinum toxin had less than half of the number of headaches they had originally experienced.

What are the terms of the NICE approval?
Two treatments of Botulinum toxin are initially tried in chronic migraine (defined as headaches on at least 15 days each month, with migraine on at least 8 of these days). The NICE guidelines state that to receive Botulinum toxin you should:

- have already tried at least three different drug treatments to prevent chronic migraine but these treatments have not worked
- not be taking too many painkillers or using them too often

If your migraine has not responded to Botulinum toxin treatment (the number of migraine headaches experienced has not decreased by 30% after two treatment cycles) then the treatment is stopped. Should chronic migraine change to episodic migraine (if the number of headaches you are having decreases to less than 15 days of headache each month for three months) then treatment with Botulinum toxin will be reviewed.
How does Botulinum toxin help to treat chronic migraine?
How Botulinum toxin helps with chronic migraine is not yet fully understood. It is thought that Botulinum toxin may reduce the transmission of pain messages to the brain. This may then have a knock-on effect on the central pain processing systems that generate migraine headaches.

What do you need to do before you can be considered for this treatment?
- You need to have tried at least three different drug treatments for chronic migraine but these treatments have failed to work.
- You should not be taking too many painkillers which may cause a 'medication over-use headache'.
- You need to have completed a headache diary for one month prior to the start of Botulinum toxin treatment.

What does the treatment involve?
The treatment involves 31 injections of Botulinum toxin into the muscles around the shoulders, neck and head. These injections are repeated twelve weeks after the first course of treatment.

Are there any side effects?
In the clinical trials Botulinum toxin was well-tolerated. The commonest side effects were 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 Botulinum toxin in headache. The injections themselves are not usually painful to receive and feel like a sharp needle prick.

What to do after treatment?
It will be necessary to stay for a short while after treatment until comfortable. A detailed headache diary will need to be completed to record the frequency of headaches occurring post injections.

It is advised that rubbing the injection sites be avoided for the first twenty four hours and hair washing should be delayed for the same period. Travelling home independently should be possible post treatment.

Who might benefit from Botulinum toxin for chronic migraine?
Only patients with chronic migraine are helped by this treatment. There are, however, other treatments available to patients with chronic migraine. It is important that patients have an informed discussion of their headaches and their options for treatment with a practitioner experienced in the diagnosis and management of headaches before a decision to use Botulinum toxin is taken.

Produced by: Dr N Fletcher & Gill Medley based upon Dorman, P and Hurst, S (2014) Botulinum toxin for chronic migraine patient information leaflet
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