

# Botox<sup>®</sup> treatment for chronic migraine



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This information booklet discusses the use of Botox® for the treatment of chronic migraine at Salford Royal NHS Foundation Trust.

**Botulinum Toxin Type A** (known as Botox®) was approved by the National Institute for the Health and Care Excellence (NICE) in June 2012 for the treatment of chronic migraine in selected adults.

## What is Botox®?

Botox® is a toxin produced by a bacterium called Clostridium Botulinum. High doses of Botox® are known to cause paralysis of muscles.

Botox® was first introduced in medical practice in the 1970s to treat squints. Since then it has found uses in other areas of medicine and more recently in the treatment of chronic migraine.

## Botox® and headache

In the mid-1990s a number of people who were receiving Botox® for cosmetic reasons reported an improvement in their headaches. Clinical trials of Botox® in various types of headache followed.

The results of these studies suggested that patients with chronic migraine might benefit from Botox® injections.

## What is chronic migraine?

This is a headache disorder in which there are at least 15 days of headache each month. A minimum of 8 of these must be typical for migraine-type headaches.

Migraine headaches are often associated with sensitivity to light, sound and movement, nausea and are throbbing in nature.

## What is the evidence that Botox® can help with chronic migraine?

Two large trials (PREEMPT trials) recruited 1384 patients with chronic migraine. These patients were selected at random and treated with either Botox® or a placebo (injections of saline, salty water).

These patients were suffering on average 20 days of headache each month, of which 18 were moderate to severe. Those treated with Botox® received 31 injections into specific sites in the scalp and neck every 12 weeks over 56 weeks.

After 12 months, 70% of those treated with Botox® had less than half of the number of headaches.

The placebo group saw a 30% response to the injections, compared with a 40% response from the real injection giving a difference of 1.8 fewer headache days per month in the Botox® group.

## How do we decide whether Botox® is appropriate?

In order to receive Botox® you should:

- Have a diagnosis of chronic migraine
- Have already failed to respond satisfactorily to at least three different migraine preventatives. These medications should have been taken for at least 3 months each at maximum tolerated doses
- Not be taking too many painkillers or triptans on a regular basis
- A headache diary has been completed for one month before the start of Botox® treatment
- If your migraine does not respond after 2 courses of Botox®, then treatment will be stopped
- If it is effective, treatment is usually continued for 1 year and then stopped

## How does Botox® help treat chronic migraine?

How Botox® works in chronic migraine is not fully understood.

It is thought that Botox® may reduce the transmission of pain messages to the brain. This may reduce over-activity in the part of the brain which generates migraines.

## What does the treatment involve?

The treatment involves 31 injections of Botox® into the muscles around the shoulders, neck and head.

These injections are repeated every twelve weeks.

## Are there any side effects?

The commonest side effects are:

- Neck pain (6.7%)
- Muscular weakness (5.5%) and
- Drooping of an eyelid (3.3%)

No serious irreversible side effects have ever been reported in trials of Botox® in headache.

The bottle of botulinum toxin also contains a tiny amount of human albumin. This is a protein taken from blood donations. There is a theoretical risk of spreading viral or other infectious germs from the blood of the donors.

The injections themselves are not too painful to receive and feel like a sharp needle prick.

**If you are taking any blood thinning medication (anticoagulants) please let your consultant or specialist nurse know as special precautions may need to be undertaken.**

**These include:**

- Warfarin
- Dabigatran
- Apixaban
- Rivaroxaban



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Unique Identifier: NOE58(17)  
Review Date: February 2020

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