

Final report summary:

Can Botox improve use of the arm and hand after stroke?

PrOMBIS (Predicting Outcome and Measuring Benefit from botulinum therapy in Stroke).

PROJECT CODE: TSA 2008-01

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Why did we fund this research?

It is thought that about half of all stroke survivors with arm and hand weakness after stroke will not make a full recovery of their movement^{1,2}. This could be for many reasons.

One such reason is spasticity, which is the constant contraction of a muscle. After a stroke, the damaged brain may not be able to send co-ordinated signals to the muscles of the arm and hand, and instead send them a message to contract all the time. If left untreated, a muscle affected by spasticity can become stiff and tight, and interfere with normal arm and hand movement. This can greatly affect a person's ability to go about important tasks of daily living and their quality of life^{3,4}.

It is therefore extremely important to be able to prevent spasticity or at least reduce its effects on the arm and hand movement of a stroke survivor.

Treatment of spastic muscles can involve physiotherapy which includes stretching the muscles to increase their range of motion. Another, newer treatment for treating spastic muscles is to inject them with a drug called botulinum toxin, commonly known as 'Botox'. The effect of Botox is to partly paralyse the muscle, reducing its ability to contract and consequently develop stiffness.

Previous studies have shown that Botox can reduce over-activity in the muscles affected by spasticity, and make the arm and hand less stiff⁵.

However, no studies have yet been able to show that, when used together with physiotherapy, Botox can help improve the ability to actively use the hand and arm in functional tasks. To answer this question, the current study is investigating whether treatment with injections of Botox, alongside a programme of physiotherapy, is better than physiotherapy alone in helping stroke survivors with arm and hand weakness.

Findings from the study could provide a more accurate prediction of who will benefit from Botox treatment, and this would inform both clinical practice and the design of future intervention trials.

What did the researchers do?

The study recruited 28 participants, who were at least three months post stroke, to a small, phase II, randomised controlled trial (RCT). They were randomised to be given either botulinum toxin (Botox) injections or placebo (dummy) injections. All participants followed a standardised, effective physiotherapy programme for the hand and arm (10 sessions over four weeks), and were assessed at one and three months after randomisation to the trial.

There were many parts to the assessment, but the main part was the measurement of functional use of the arm and hand. This was measured through a specialised task in which the participant's ability to grasp and release a drinking glass to and from a target was recorded. Also assessed were changes in arm and hand spasticity, as measured by a specially developed motor device, which held the arm, and recorded its stiffness as the arm was passively moved by a physiotherapist.

The trial was 'double-blinded' so that neither the participant, nor the researchers involved with the participants, knew who received the Botox and who received the placebo.



What did the research find?

The findings of the trial were published in the International Journal of Stroke in November 2014⁶.

It found no evidence of a significant difference in the main outcome measure (grasp-release time of drinking glass) between the Botox and placebo injection treatment groups. Across twenty other secondary outcomes measuring arm and hand spasticity, strength, and quality of life, there was some suggestion that patients in the Botox group had reduced spasticity of the muscles that flexed the fingers, but no other differences were observed.

Both groups achieved the physiotherapy treatment goals (65% in the placebo group and 71% in the Botox group), with improvements in angle of wrist extension, meaning the ability to tilt the wrist away from the palm (placebo +9 degrees, Botox +11 degrees), and improvement on the ARAT (Action Research Arm Test) score of functional arm and hand mobility (placebo +3 points, Botox +5 points).

Therefore, this trial found that standardised upper limb physiotherapy was effective in achieving patient goals with or without the use of Botox.

As Botox did not improve active functional outcomes, this costly treatment may not need to be administered to patients with arm and hand weakness after stroke on the NHS.

What does this mean for stroke survivors and those at risk?

This study suggests that Botox may not be effective in helping with arm and hand recovery after stroke, when used in conjunction with physiotherapy.

However, due to the small size of the trial, no definitive conclusions can be drawn.

Larger trials would be needed to reliably show whether Botox may be of benefit or not.

References

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