



CLINICAL STUDY RESULTS

A Study Comparing the Muscle Action Potential effects of Dysport, Botox, and Xeomin in the Foot Muscle in Healthy Male Volunteers

The results of this study suggest that the muscle action potential effects of Dysport[®], Botox[®], and Xeomin[®] all last a similar length of time.

The results shown in this summary are from one clinical study. Other clinical studies may produce different results.

This lay summary has been produced by a company independent of Ipsen. It has been reviewed by employees of Ipsen, and a group of participants or people from a non-scientific background.

What was the study about?

This study compared the ‘muscle action potential’ in participants’ foot muscles after being injected with either Dysport® (an Ipsen product), Botox® or Xeomin®. ‘Muscle action potential’ is measured in the muscle as an electrical signal when the muscle receives a signal from the nerve it is connected to.

All three of these drugs contain ‘Botulinum toxin type A’ , a substance that blocks certain chemical signals that cause muscles to tighten and shorten (contract). Injection of these products into muscles is used to treat certain muscular conditions and cosmetically to improve the appearance of wrinkles.

This study was performed to check the results of an earlier study (performed in a laboratory, not in people). This earlier study suggested that the three study treatments could have a different duration in muscles. A longer duration has potential benefits for patients, such as a longer period of symptom relief between injections.

The aim of this study was to compare the muscle action potential of Dysport, Botox and Xeomin after 28 weeks to see which, if any, lasted longer.

The study took place between July 2021 and June 2022 at one study site in the United Kingdom.

Participants were assigned randomly to receive either Dysport, Botox, or Xeomin (known as ‘randomization’).

Neither the participants nor the study team were told which treatments the participants would receive (known as ‘double-blind’).

On the first day of the study, participants received a single injection of either Dysport, Botox or Xeomin into one of their foot muscles. The muscle injected was one involved with extending the middle three toes. This muscle was chosen because it would permit measuring the electrical signal but would not interfere with walking.

Participants’ health was monitored for up to 40 Weeks.

Who took part in this study?



HEALTHY MALE VOLUNTEERS



35 YEARS AVERAGE AGE

To be eligible to take part in the study, participants had to be:



- healthy
- male
- 18 to 65 years old
- within a certain weight range

Participants were not eligible to take part in the study if they had:



- history of certain medical conditions
- disease that affects nerve and muscle function
- a history of muscle related issues such as breathing, swallowing, speaking and vision problems

What treatments were used?

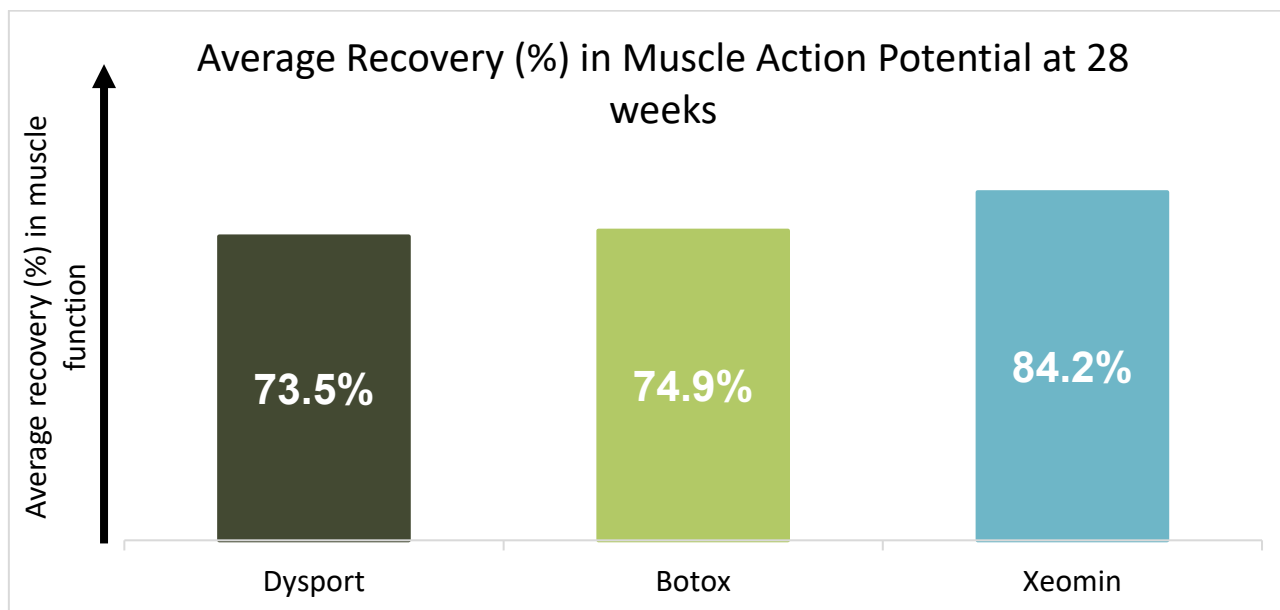


How did Dysport affect muscle action potential after 28 weeks compared to Botox or Xeomin?

Using electrodes, researchers compared the 'muscle action potential' in the foot muscle before the injection and again 28 weeks later.

The figure below compares the average recovery (as a percentage %) in muscle action potential 28 weeks after the injection. 100% recovery would mean the treatment had completely worn off, and muscle function had fully recovered. The lower the percentage the more the treatment was still having an effect. At 28 weeks, none of the treatments had worn off completely (100%); all three treatments were still having an

effect, but the difference between the three treatments was not considered significant.



After 28 weeks there was no significant difference in how long the effect of Dysport lasted compared to Botox or Xeomin.

How did the treatment make participants feel?

During the study, participants were asked to report any 'adverse events', i.e. if they felt unwell, experienced any kind of medical event, or noticed anything different about their bodies. Researchers recorded *all* adverse events reported by participants, whatever the cause. For example, some participants caught COVID-19 and this was reported as an adverse event, although it wasn't related to the study treatment.

If the study doctor thinks an adverse event may be related to the study treatment, it is called a 'side effect' or a 'treatment-related adverse event'. An adverse event or side effect is considered 'serious' when it is life-threatening, causes lasting problems, or leads to hospitalization.

- Adverse events that are *life-threatening*, cause lasting problems or require an individual to go to the *hospital* are considered *serious*.
- *No participant* in this study experienced a serious treatment-related side effects.







Not all the adverse events reported were considered related to the treatment. Overall, 6 out of 45 participants (13%) experienced *treatment-related* side effects:

- 1 out of 15 participants (7%) who received **Dysport**
- 3 out of 15 participants (20%) who received **Botox**
- 2 out of 15 participants (13%) who received **Xeomin**

No participant stopped taking part in the study because of a side effect or treatment-related adverse event.

Treatment-related adverse events are shown in the table below, both as a percentage (%) followed by the actual number of participants in the group (e.g. 1 out of 15 or 7%).

None of adverse events reported were severe enough to prevent the participant’s daily activities.

Side Effects	Dysport (15 Participants)	Botox (15 Participants)	Xeomin (15 Participants)
Numbness	7% (1 out of 15) 	7% (1 out of 15) 	0% (0 out of 15)
Unusual tingling or crawling feeling	0% (0 out of 15)	7% (1 out of 15) 	7% (1 out of 15) 
Muscle pain	0% (0 out of 15)	0% (0 out of 15)	7% (1 out of 15) 
Pain in hands or feet	0% (0 out of 15)	7% (1 out of 15) 	0% (0 out of 15)

More information

To learn more about this study, please visit the [ClinicalTrials.gov](https://clinicaltrials.gov) website and search for study NCT04970407.

For more information about current treatments available, please speak to your healthcare provider. If you have any questions about this study, please contact the sponsor, Ipsen at:

 clinical.trials@ipson.com

Future research

There is no future research planned on this topic.

Study identification and other information

Full study title: A Phase I, Randomised, Double-Blind, Parallel-Group, Single-Centre Comparative Study to Evaluate the Pharmacodynamic Profile of Dysport, Botox, and Xeomin in the Extensor Digitorum Brevis Model in Healthy Adult Male Participants.

STUDY NUMBERS: Europe: 2021-000802-14 | United States: NCT04970407 |

Protocol: D-FR-52120-279.

OTHER INFORMATION: Phase I studies can take several months to years to complete and look at how safe a potential new treatment is. Some changes were made during the study to ensure safety, improve recruitment, make having the injections easier, and clarify information in the study protocol (i.e. the researcher's guide to the study).

We thank all the volunteers who took part in this study. Without their support, advances in treatments for medical conditions would not be possible.

We would also like to thank the people who took the time to review this document to make it easier for a general audience to read.