CLINICAL STUDY RESULTS

DIRECTION: A study to compare the safety and effectiveness of Dysport® and Botox® in adults with upper limb spasticity

Overall, the results suggest that Dysport® is as safe as Botox® in adult participants with upper limb spasticity. Additionally, the results for this study suggest that the effect of Dysport® lasted three days longer than the effect of Botox®.

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

This lay summary was created by Ipsen with the assistance of a third-party writing service provider

CLIN-52120-452
June 2026

What was the study about?

The purpose of this study was to compare the safety and how long the effect lasted for the two marketed Botulinum Neurotoxin Type-A (BoNT-A) medicines in adults with upper limb spasticity (ULS). These medicines were abobotulinumtoxin-A, called Dysport® and onabotulinumtoxin-A, called Botox®.

Upper limb spasticity means spasticity in the arms and/or hands including wrists and fingers. Spasticity is a condition that affects the brain or nerves and causes the muscles to become stiff, tight, and difficult to control. Spasticity of the arms can make it difficult to move the arms normally, which can cause pain, discomfort, and restrictions on doing everyday tasks.

BoNT-A is used for the treatment of ULS. It blocks certain chemical signals that cause muscles to tighten and shorten (contract). BoNT-A helps relieve symptoms, improves movement, and delays the deformities that may need surgery.

Dysport® and Botox® are approved for different conditions that affect muscle activity in multiple countries including the United States, Canada, and France.

In this study, researchers wanted to compare the safety and effectiveness of Dysport® with Botox®.

> The aim of this study was to compare the safety of Dysport® and Botox® and to learn how long their effect lasted in adults with upper limb spasticity.

The study took place between June 2021 and August 2025 at 72 study sites in the United States, Canada, and France.

Who took part in this study?

464
PARTICIPANTS

306
MEN

158
WOMEN

57 YEARS
AVERAGE AGE

To take part in the study, participants had to:

- Be aged 18 to 80 years,
- Have stable ULS for at least 3 months, with only 1 arm that required treatment. Participants from Canada needed to have stable ULS, caused specifically by a stroke, for at least 3 months,

- Have the need for a BoNT-A injection in all the 5 specified muscles in the wrist, fingers and upper arm,
- Require increased effort and/or assistance with normal activities or had limited normal activities in the target muscle for this study,
- Have increased muscle tightness in at least one of the target muscles for this study and in at least one other muscle. This was checked by testing the movement of joints in the affected upper limb, which affects wrist, fingers and elbow muscle. It was tested if the affected muscles could be moved easily or were difficult to move even with help, or if the upper limb was stiff and stuck in one position.

Participants could not take part in the study if:

- They had a health condition(s) or had received treatment(s) that could affect the result of the study.

What treatments were used in this study?

Study Treatment	Other Treatment
Dysport® was given as 5 injections in 5 different muscles of the arm, wrists and fingers at a total dose of 900 Units on the first day of treatment.	Botox® was given as 5 injections in 5 different muscles of the arm, wrists, and fingers at a total dose of 360 Units on the first day of treatment.

The doses of Dysport® and Botox® used in this study are the approved recommended doses for ULS in the participating countries. Each BoNT-A medicine has its own dose because they are made differently. These doses cannot be used interchangeably.

This study had 2 steps: a screening period, and a treatment period. Both steps are detailed below.

Screening: The study doctor checked if participants could take part in this study within 3 weeks before starting the study treatment.

Treatment:

There were 2 treatments in this study: Dysport® and Botox®. The study was planned so that all participants received both treatments, but the sequence in which they received treatments was randomly decided for each participant. This is called a "crossover" study.

464 participants received treatment in nearly equal numbers to one of the below treatment sequences:

- **Dysport®** as first treatment and then **Botox®** as second treatment, or
- **Botox®** as first treatment and then **Dysport®** as second treatment.

This sequence was randomly assigned using a computer system. This process is called randomisation. It means that each participant could be assigned to any sequence, and it helps to make sure that the participants were divided in a balanced and fair way.

This study was "double-blind". This means that neither participants nor the researchers knew who was given Dysport® or Botox® first in the treatment sequence. Studies are sometimes done this way to make sure that study results are not biased by this information.

After the first treatment on Day 1, the participants visited the study site at Week 1, Week 4, Week 10, and Week 12. At these visits, they were checked for muscle tightness, and their safety.

At Week 12, the study doctor decided if the participant met treatment rules for second treatment or not. If the participant met the treatment rules, they received the second treatment. If they did not meet the treatment rules, they continued the check-ups, once a month, at Week 16, Week 20, and Week 24. At these visits, the participants were checked again to see if they met the treatment rules for second injection. If they did, they received the second treatment. If not, they stopped taking part in the study after Week 24.

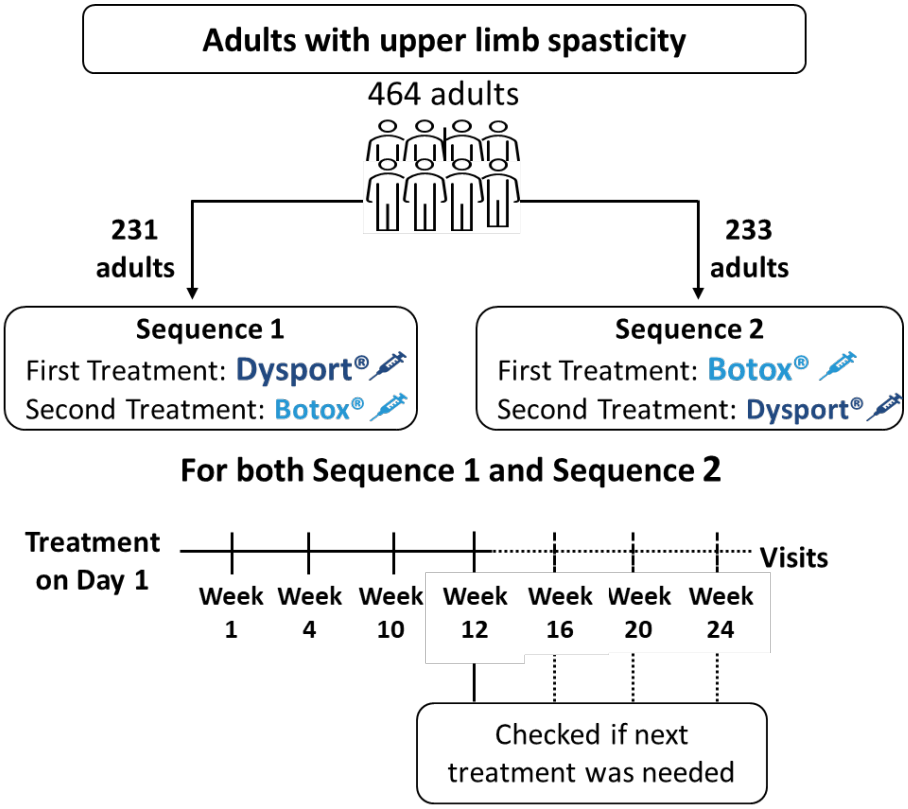
After the second injection, the participants visited the study site with the same visit schedule as after the first treatment.

The study ended at Week 24 after the second treatment or when the study doctors assessed that the participant needed more treatment for ULS.

Throughout the study, participants were checked for their safety. They were asked to complete health related questionnaires, physical examinations, and other clinical check-ups.

An individual participant was in the study for a maximum of 1 year.

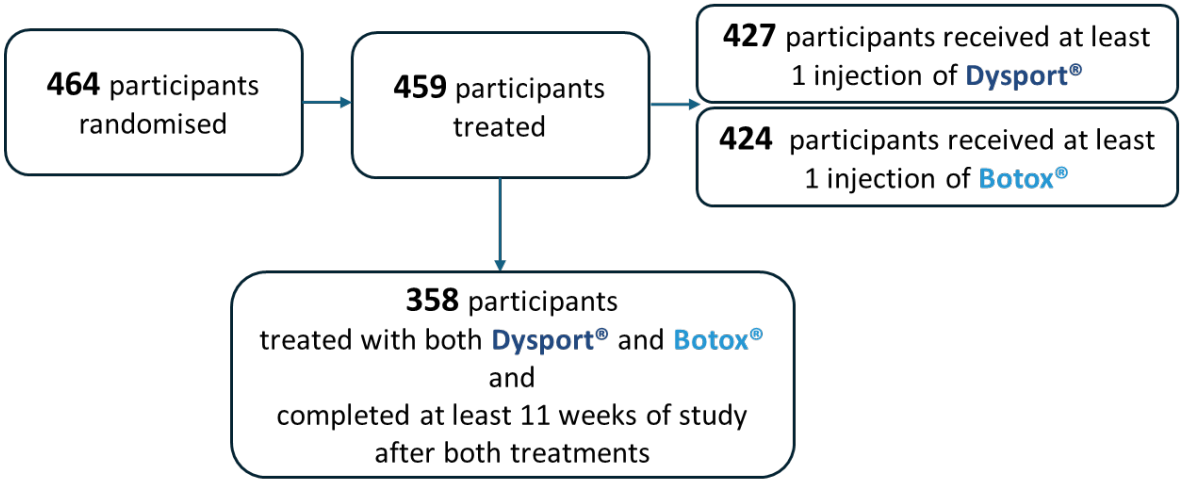
The figure on the next page shows how the treatment and visits happened during the study.



During the study, of the 464 participants who were randomised, not all participants received treatment because of one of the following reasons:

- the participants could not be contacted for next steps,
- they had a medical problem, or
- they either stopped taking part in the study by their own choice or because of the study doctor's decision.

The figure below shows how many participants received what treatment.



What did researchers find out in the study?

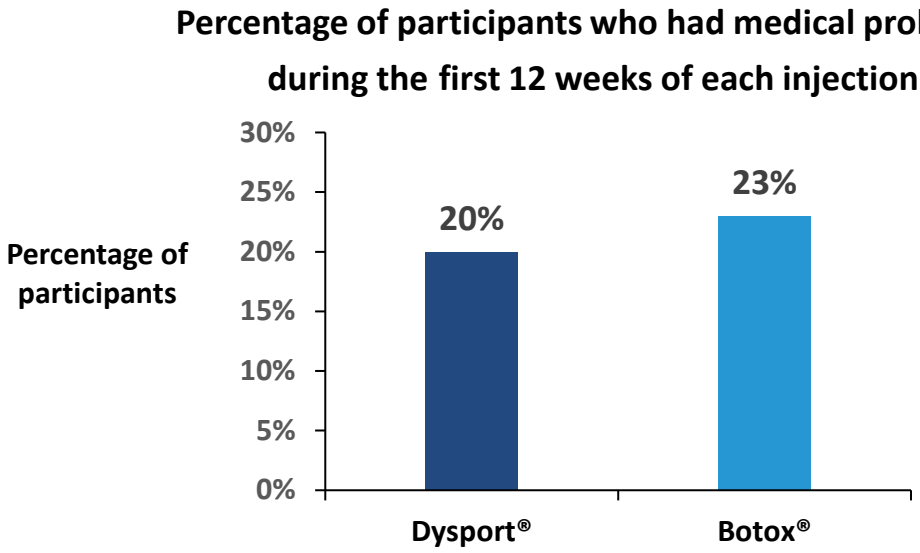
Within the first 12 weeks of each injection, medical problems were reported in 20% of participants when they received Dysport® and 23% of participants when they received Botox®.

The researchers found that Dysport® was as safe as Botox® in adult participants with ULS.

A medical problem, also called an 'adverse event', is any change in participants' health that they may experience, for example, if they felt unwell, experienced any kind of medical event, or noticed anything different about their bodies. These medical problems could be related or not related to the study treatments.

How many participants had medical problems with Dysport® compared to Botox® during the first 12 weeks of each injection?

The researchers recorded the number of participants who had medical problems during the 12 weeks after the injection with both Dysport® and Botox®.



The 358 participants out of the 459 participants who received both Dysport® and Botox® and completed at least 11 weeks after both treatments were included in these results. 101 participants were not included as they either did not get the second treatment, did not complete the required visits after injection or no longer met the study treatment rules.

How long did the treatment continue to work before another dose was needed when treated with Dysport® compared to Botox®?

The researchers found that the effect of Dysport® lasted three days longer than the effect of Botox®. The researchers assessed that these results were not due to chance.

How did the treatment make participants feel?

During the study, participants were asked to report any 'medical problem' or 'adverse event', that is, 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, if a participant caught COVID-19, this was reported as an adverse event, although it was not related to the study treatment.

A medical problem is considered 'serious' if it results in death, is life-threatening, causes lasting problems, or leads to hospitalisation.

The websites listed at the end of this summary may have more information about the medical problems that happened in this study.

Medical problems displayed here are from the start of the study until the end of the study, for all the participants who received at least one dose of either Dysport® (427 participants) or Botox® (424 participants). These medical problems could be related or not related to the study treatments.

- 5% (21 out of 427 participants) who received Dysport® and 5% (20 out of 424 participants) who received Botox® experienced serious medical problems in this study.
- Of these, 1 participant who received Dysport® and 1 participant who received Botox® died due to a medical problem during the study.
- No serious medical problems and death were considered related to the study treatment.

Overall, medical problems from the start of the study until the end of the study were reported by:

- 23% (96 out of 427 participants) who received **Dysport®**
- 25% (107 out of 424 participants) who received **Botox®**

There were 2 participants in each treatment group who stopped taking part in the study because of a medical problem.

The most commonly reported serious medical problems that happened in 2 or more participants in any group are shown below.

Commonly Reported Serious Medical Problems		
Serious Medical Problems	**Dysport® (427 Participants)**	**Botox® (424 Participants)**
Fits	1% (5 out of 427)	Less than 1% (2 out of 424)
COVID-19	Less than 1% (4 out of 427)	0% (0 out of 424)
Kidney infection	Less than 1% (2 out of 427)	0% (0 out of 424)
Infection from use of a medical device	0% (0 out of 427)	Less than 1% (2 out of 424)

The most commonly reported medical problems that happened in 4 or more participants in any group are shown below.

Commonly Reported Medical Problems		
Medical Problems	**Dysport® (427 Participants)**	**Botox® (424 Participants)**
COVID-19	1% (6 out of 427)	2% (8 out of 424)
Fall	1% (6 out of 427)	2% (9 out of 424)
Fits	1% (6 out of 427)	Less than 1% (2 out of 424)
Headache	Less than 1% (4 out of 427)	1% (6 out of 424)
Pain in the arms or legs	Less than 1% (4 out of 427)	Less than 1% (4 out of 424)
Rash	Less than 1% (4 out of 427)	Less than 1% (2 out of 424)
Weakness in muscle	Less than 1% (4 out of 427)	Less than 1% (2 out of 424)
Common cold	Less than 1% (3 out of 427)	Less than 1% (4 out of 424)

Commonly Reported Medical Problems		
Medical Problems	**Dysport® (427 Participants)**	**Botox® (424 Participants)**
Infection of the parts of the body that collect and pass out urine	Less than 1% (3 out of 427)	Less than 1% (4 out of 424)
Muscle cramps	Less than 1% (1 out of 427)	Less than 1% (4 out of 424)
Nose and throat infection	Less than 1% (1 out of 427)	Less than 1% (4 out of 424)

More information

To learn more about this study, please visit:

- ClinicalTrials.gov and search for study NCT04936542 or
- Search for clinical trials - EMA (euclinicaltrials.eu) and search for study 2023-509196-16-00.

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@ipsen.com

Future research

There is no future research planned with Dysport® for ULS.

Study identification and other information

FULL STUDY TITLE: A Multicentre, Interventional, Post-Marketing, Randomized, Double-Blind, Crossover Study to Evaluate the Clinical Safety and Efficacy of Abobotulinumtoxina (Dysport®) in Comparison with Onabotulinumtoxina (Botox®) When Treating Adults with Upper Limb Spasticity

STUDY NUMBERS: Europe: 2023-509196-16-00| United States: NCT04936542 |

PROTOCOL: CLIN-52120-452.

OTHER INFORMATION: 'Phase 4' or 'Post-Marketing' studies are done to learn more about the safety, benefits, and risks of an approved drug.

We thank all the participants 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 general audience to read.