Dyston®

| Botulinum Toxin Type A |

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Evalution of the safety and efficacy of a biosimilar abobotulinum toxin type A in treating moderate-to-severe glabellar lines: A non-inferiority double blinded randomized controlled trial

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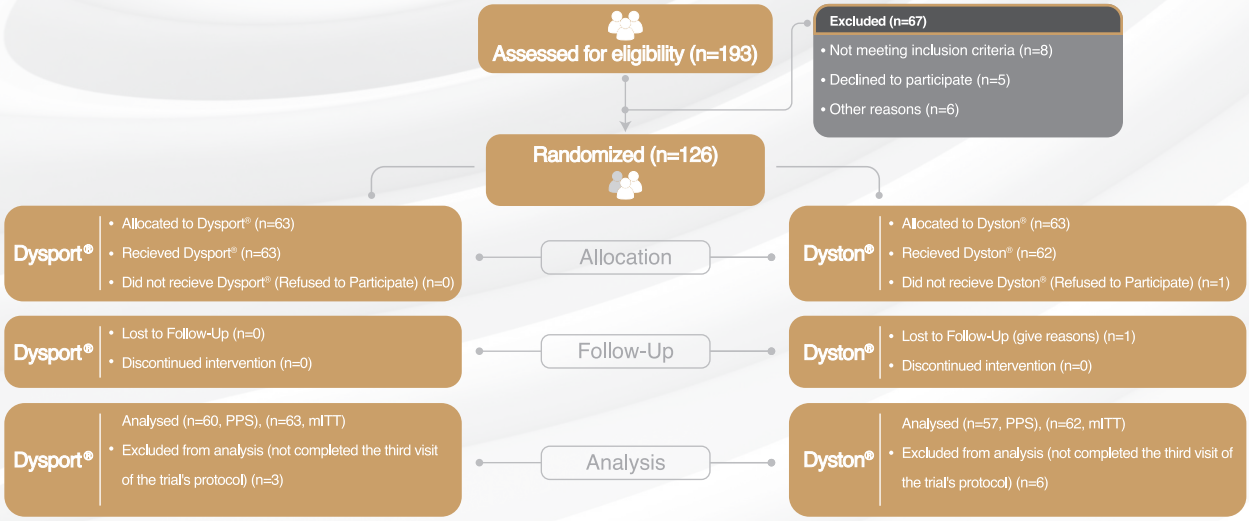
Introduction

This study is conducted to compare the safety and efficacy of Dyston® (investigational biosimilar abobotulinum toxin A) with Dysport® (abobotulinum toxin A, Ipsen) in the treatment of moderate-to-severe glabellar lines.

Method

Out of 193 screened subjects, 126 volunteers with moderate-to-severe glabellar lines fulfilling eligibility criteria were randomized in a 1:1 ratio to receive either an intramuscular injection of 40–60 units of Dyston® or Dysport®.



Primary Objective

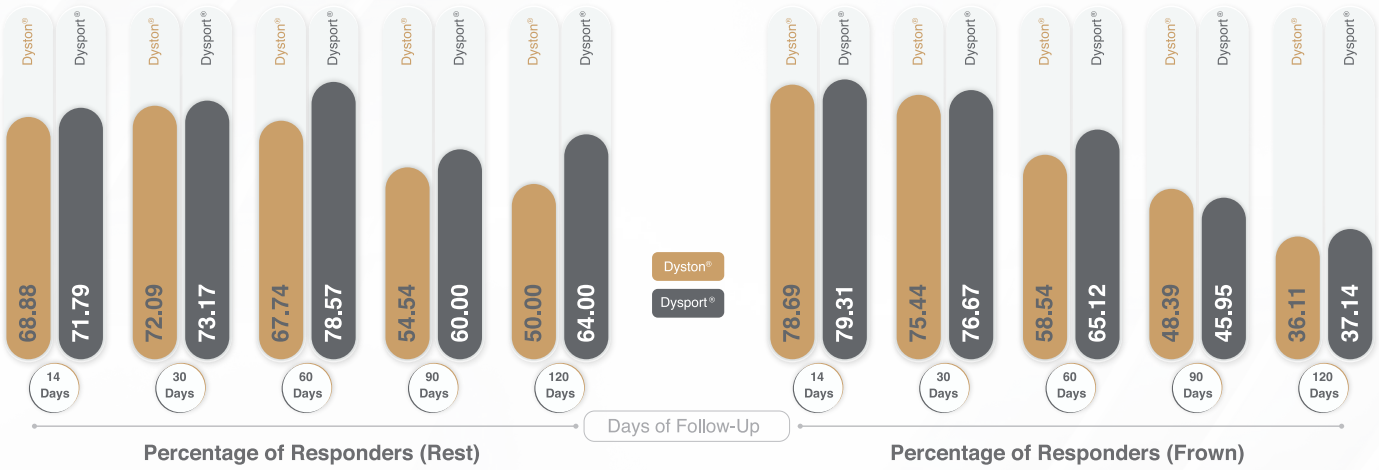
To test the non-inferiority of Dyston® compared with Dysport® as measured by the percentage of volunteers who achieved no or mild glabellar lines at maximum frown assessed by the physicians based on the Glabellar Line Severity Score (GLSS) at Day 30.

Secondary Objective

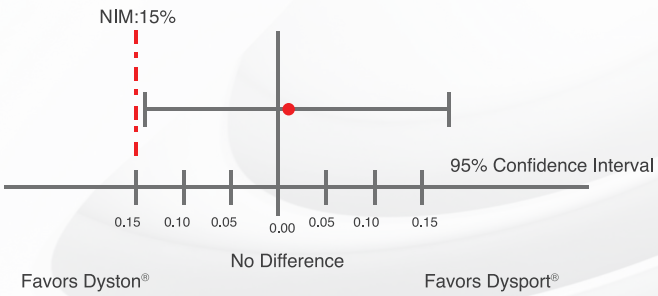
Improvement in the glabellar lines at maximum frown and rest states at Days 14, 30, 60, 90, and 120 as well as the side effects of the treatment.

Results

Treatment of moderate-to-severe glabellar lines with Dyston® was effective, tolerable, and non-inferior compared with Dysport®.



Results of the efficacy endpoints are presented as percentage of responders (the participants who had mild or no glabellar lines according to the physician assessment based on glabellar line severity scale) at rest and frown states in each follow-up visit (day 14, 30, 60, 90 and 120). There was no significant difference between groups.



Comparison of the primary endpoint (response rate at maximum frown at day 30 of injection) in Dyston® and Dysport® group. (p value: 0.88, 95% CI: –14.24 to 16.70, diff: 1.23) as per protocol set.

Further post marketing authorization studies is recommended to assess the duration of Dyston® action, efficacy in other indications, and to observe whether Dyston® would cause rare adverse events.

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