Satisfaction study of split doses botulinum toxin with double frequency

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This study has been transitioned to CTIS with ID 2025-520915-14-00 check the CTIS register for the current data. Primary objectiveTo investigate the client*s satisfaction over time for the treatment of glabellar frown lines (GFL), horizontal...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49792

Source
ToetsingOnline

Brief title
Split dose double frequency study

Condition

- Other condition

Synonym
rhytide, wrinkle

Health condition

cosmetic treatment

Research involving
Human

Sponsors and support

Primary sponsor: Flack Clinic
Source(s) of monetary or material Support: Pharmaceutical industry

Intervention

Keyword: Aesthetic, Botulinum toxin Type A, Efficacy, Satisfaction

Outcome measures

Primary outcome

- Satisfaction Scale - score of treatment satisfaction over time compared with base-line.

Secondary outcome

- Satisfaction Scale - score of treatment satisfaction before Treatment 3 (after 4 months), and at the Follow-up visit (after 8 months);

- Satisfaction Scale - difference in satisfaction score between the IG and CG for each time point;

- Merz Aesthetics Scales in dynamic - at least one-point improvement on the Merz Aesthetic Scales in each of the treatment areas;

- GAIS - score of at least *improved*;

- Antera 3D camera - Wrinkle depth quantification (mm);

- Canfield Vectra H2 - Wrinkle depth quantification (mm);

- MoistureMeter SC Compact - quantification of increase in hydration compared to baseline in the stratum corneum of the dermis (arbitrary units) compared with baseline;

- ElastiMeter - quantification of increase in elasticity (instant skin elasticity [N/m]) compared with baseline;

- VapoMeter - quantification of decrease in TEWL (evaporation rate value

[g/m²h]) compared with baseline;

- SebumScale - quantification of decrease in sebum production (amount of sebum

[mg/cm²]) compared with baseline;

- BeautyQoL - change in score on QoL.

Study description

Background summary

The field of aesthetic medicine focuses to minimizing signs of aging such as skin laxity, wrinkles, and improve overall appearance. Treatments aims to improve the perceived health and well-being of the client. For more than 20 years, botulinum toxin has been known for its applicability in aesthetic practice.Through its property to induce muscle relaxation, the toxin is approved by the EMA for the treatment of hyperactive facial lines, including glabellar lines and horizontal forehead lines and crow*s feet.

The aim of this study is to evaluate the satisfaction of the client and physician, as well as the pharmacodymanics of NT201 in two dosing regimens: the standard regimen (control group) and a regimen with half the dose and a higher injection frequency (intervention group).

Study objective

This study has been transitioned to CTIS with ID 2025-520915-14-00 check the CTIS register for the current data.

Primary objective
To investigate the client*s satisfaction over time for the treatment of glabellar frown lines (GFL), horizontal forehead lines (HFL) and lateral periorbital wrinkles, with half the stand-ard dose of NT201 administered at more frequent intervals (intervention group; 2 months interval) and the standard dose (control group; 4 months interval) measured with an elec-tronic visual analogue scale (eVAS).

Secondary objective
· To evaluate the client*s satisfaction 4 and 8 months after baseline compared with baseline for each of the treatment areas.
· To compared the differences in client satisfaction of the intervention group

com-pared with the control group during each visit for each of the different treatment ar-eas.
· To evaluate improvement of the appearance at every study visit, using the Global Aesthetic Improvement Scale (GAIS).
· To evaluate the wrinkle reduction using the Miravex Antera 3D imager, the Canfield Vectra H2 3D camera, and the respective Merz Aesthetics Scales.
· To evaluate the changes in hydration, elasticity, transepidermal water loss and se-bum production in the treated areas.
· To evaluate the impact on quality of life of clients in the intervention group and con-trol group.

Study design

This will be a double-blind, randomized controlled study.

Intervention

Clients will be randomized in a 1:1 ratio into the intervention group (IG) or control group (CG). The IG will be treated with half of the standard dose (Table 1 of protocol) of NT201 at every visit. The CG will be injected with the standard dose (Table 1 of protocol) of NT201 every 4 months (1st and 3rd treatment). To ensure blinding, clients in the CG will be treated with a placebo during treatment 2 and 4.
An overview of the dosages can be found in table 1 of the protocol (page 13).

Study burden and risks

Seeking for beauty, many of the clients address to the aesthetic physician requesting a natural result, a fresher look, and a well-rested appearance. Therefore, the treatment with NT201 has a major role by reducing muscle contraction in the treated area. By following the standard protocols and doses of the injection techniques, subjects have also noticed, especially in the first weeks after treatment, that the inability to use mimic muscles may lead to an artificial, frozen appearance. By reducing the dose and increasing the frequency of botulinum toxin injection, this study attempts to increase cliient satisfaction by establishing a more natural appearance right from the debut of the toxin's effect. Because of a split-face study design, asymmetry due to different doses of NT201 might occur. Clients may withdraw from the study at any time. A corrective treatment will be offered, without additional costs.
The potential risks of the procedures are minimal and they are related to the injection techniques or allergic reactions. Considering that the physicians in charge are members of the Dutch Society of Aesthetic Medicine (NVCG), who have followed an extensive training program and have an extensive experience, the risks will be even lower.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

· Males or females, 18 to 65 years of age, inclusive;
· General good health status
· Symmetrical rhytids on both sides of the face, expressed by a Merz Aesthetics Scales score in dynamic >= 2 in all treatment areas;
· Client overall satisfaction score >= 2 and <= 8 based on the eVAS Satisfaction Scale (0-10);
· Able to participate and willing to give informed consent and comply with the study re-strictions.

Exclusion criteria

· Clients with known allergies or sensitivity to the drug or any components of the study medication;
· Use of any agent that impedes the neuromuscular transmission, or other neuromus-cular diseases that could amplify the effects of botulinum toxin type A treatment (e.g. myasthenia gravis, excessive weakness, Eaton-Lambert syndrome, or atrophy of target muscles);
· Previous exposure to botulinum toxin < 6 months before the first treatment;
· Has ever received a permanent filler in the upper face, or has received a temporary filler in the upper face in the last two years;
· Presence of an infection, or any type of skin disease, in the treatment area;
· Presence or history of a malignancy like melanoma in the treated area;
· Grade 4 lines in one re more of the treatment areas expressed by the Merz Aesthetic Scales;
· Marked asymmetry of the crow*s feet by 1 point on the Merz Aesthetic Scales;
· Females who are pregnant, planning to get pregnant during the full duration of the study, or breastfeeding.
· Clients with body dysmorphic disorder or related diagnosis in the DSM-V.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2020
Enrollment:	96
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	NT201
Generic name:	Botulinum toxin Type A
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2025-520915-14-00
EudraCT	EUCTR2017-004278-32-NL
CCMO	NL68226.018.18