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A split-face study comparing intradermal botulinum toxin A with and without hyaluronic acid biorevitalization for facial rejuvenation

Submission date
16/10/2025

Recruitment status
No longer recruiting

Registration date
20/10/2025

Overall study status
Completed

Last Edited
20/10/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at a new way of improving facial skin quality and reducing wrinkles. Botulinum toxin type A (commonly known as BoNT-A) is already widely used to soften facial lines, while hyaluronic acid–based products can improve hydration, firmness, and radiance of the skin. This study will test whether combining both treatments in a single injection session works better than BoNT-A alone.

Who can participate?
Healthy adults between 35 and 55 years old who show early signs of skin aging, such as fine lines, wrinkles, or mild skin laxity.

What does the study involve?
Each participant receives treatment on both sides of the face in a “split-face” design. One side is treated with BoNT-A alone, while the other side is treated with BoNT-A mixed with a hyaluronic acid–based product (NCTF®135HA). The injections are given using very fine needles in small amounts. Participants are then followed up for 60 days to assess changes in wrinkles, skin hydration, tone, and overall appearance. Photos and questionnaires are also used to measure results.

What are the possible benefits and risks of participating?
The potential benefits include visible improvement in facial skin quality and wrinkle reduction. Risks are minimal but may include temporary redness, bruising, swelling, or mild discomfort at the injection site. These are expected to resolve naturally.

Where is the study run from?
The study is carried out at Mutah University Faculty of Medicine and a private facial plastic surgery clinic in Amman, Jordan.

When is the study starting and how long is it expected to run for?
The study began in July 2024 and is expected to run until February 2025, including treatment and follow-up visits.

Who is funding the study?
Investigator-initiated and funded.

Who is the main contact?
Dr Islam Alzayadneh, Assistant Professor, Department of Otolaryngology–Head & Neck Surgery, Mutah University, Karak, Jordan, izayadne@mutah.edu.jo, xayadneislam@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Mutah University IRB Approval Number 70025

Study information

Scientific Title
Streamlined facial rejuvenation: a randomized split-face trial of premixed intradermal botulinum toxin type A and hyaluronic acid biorevitalization

Acronym
BRIGHT-FACE SFR Trial

Study objectives
To evaluate the efficacy and safety of a single-session premixed intradermal botulinum toxin type A (BoNT-A) with hyaluronic acid biorevitalization (NCTF®135HA) compared to BoNT-A alone in improving wrinkle severity and skin quality parameters in adults

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/09/2025, Mutah University Faculty of Medicine Ethics Committee (Street, Mu'tah, Alkarak, 61710, Jordan; +962-3 2372380-99; abu_lubbad@mutah.edu.jo), ref: 70025

Study design
Single-centre interventional prospective randomized double-blind intra-patient split-face trial

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Facial aging (dynamic wrinkles, skin quality deterioration)

Interventions
Participants are randomized using a computer-generated random sequence in a split-face design, with one side of the face receiving intradermal botulinum toxin type A (BoNT-A) monotherapy and the contralateral side receiving a premixed formulation of BoNT-A with NCTF®135HA combination. Allocation was concealed by an independent staff member not involved in injections or evaluations. BoNT-A (20 Units of Dysport® per side, reconstituted to 20 U/mL) is administered intradermally using the microdroplet technique. For the combination side, BoNT-A is premixed with 0.9 mL of NCTF®135HA to maintain an identical BoNT-A concentration. Microinjections of 0.01–0.05 mL per droplet are delivered in a 1 cm^2 grid across the forehead, periorbital region, perioral lines, and nasolabial folds using a 32-gauge needle. The intervention is performed in a single session under topical anesthesia. Outcomes are assessed at baseline and 60 days post-treatment.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The change in wrinkle severity scores, comparing BoNT-A monotherapy versus BoNT-A + NCTF®135HA (split-face design), will be measured using the Wrinkle Severity Rating Scale (WSRS) between baseline (Day 0) and Day 60

Key secondary outcome(s))
1. The change in hydration, firmness, radiance, and tone homogeneity will be patient- and evaluator-reported using a Visual Analog Scale (VAS) from baseline to Day 60
2. Global aesthetic improvement in appearance will be measured by a blinded evaluator and patient using the Global Aesthetic Improvement Scale (GAIS) at Day 60 for each treatment side
3. The proportion of participants reporting visible side-to-side differences, satisfaction,

willingness to repeat treatment, and likelihood of recommending it will be measured using a patient satisfaction questionnaire at Day 60
4. The incidence and type of treatment-related adverse events (e.g., bruising, swelling, erythema, tightness) will be measured using case report forms up to Day 60

Completion date
28/02/2025

Eligibility

Key inclusion criteria
1. Adults aged 35 to 55 years
2. Presence of mild to moderate dynamic facial wrinkles (e.g., forehead, periorbital, perioral, or nasolabial folds)
3. Early signs of skin laxity and reduced dermal quality (e.g., hydration, tone, or radiance)
4. Willingness to refrain from other facial aesthetic treatments during the study period
5. Ability and willingness to provide written informed consent

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Upper age limit
55 years

Sex
All

Total final enrolment
52

Key exclusion criteria
1. Prior facial aesthetic procedures (botulinum toxin, dermal fillers, laser, or energy-based devices) within the past 6 months
2. Active dermatological conditions affecting the face (e.g., eczema, psoriasis, acneiform eruptions, or infections)
3. Known hypersensitivity or allergy to botulinum toxin type A or hyaluronic acid–based products
4. Neuromuscular disorders (e.g., myasthenia gravis, Lambert-Eaton syndrome)
5. History of bleeding disorders or current use of anticoagulant/antiplatelet therapy that may increase injection-related risk
6. Pregnancy or breastfeeding
7. Any systemic illness or unstable medical condition judged by investigators to pose a safety

concern or interfere with study outcomes
8. Inability or unwillingness to provide informed consent

Date of first enrolment
15/07/2024

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
Jordan

Study participating centre
Mutah University, Faculty of Medicine
Mutah street
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Study participating centre
Dr. Islam Alzayadneh, Facial Plastic Surgery Centre
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Sponsor information

Organisation
Mutah University

ROR
https://ror.org/008g9ns82

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data (IPD) will not be publicly shared due to cultural sensitivities and strict privacy considerations specific to the patient population, as well as the terms of our institutional ethics approval. The IRB-approved consent covered data use for analysis within this trial but did not extend to broader data sharing. Only aggregated, de-identified data are included in the published manuscript. Interested researchers may contact the corresponding author for further information about the study methodology: Dr Islam Alzayadneh, Assistant Professor, Department of Otolaryngology–Head & Neck Surgery, Mutah University, Karak, Jordan, izayadne@mutah.edu.jo, xayadneislam@gmail.com

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			20/10/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			20/10/2025	No	No
Statistical Analysis Plan			20/10/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes