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A study exploring healthcare professionals' experiences using a ready-to-use botulinum toxin for cosmetic treatments in UK aesthetic clinics

Submission date
12/03/2025

Recruitment status
No longer recruiting

Registration date
10/04/2025

Overall study status
Ongoing

Last Edited
10/04/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Background and study aims
Botulinum toxin is commonly used in aesthetic medicine to reduce the appearance of facial lines such as frown lines and crow's feet. A new formulation, called RelabotulinumtoxinA, has been developed that comes ready-to-use, without the need for reconstitution before injection. This may offer advantages in terms of time savings, reduced waste, and consistency of results. The PURE-QUEST study aims to understand how UK healthcare professionals working in aesthetic clinics experience using this product in real-world practice. It will also assess the broader clinical, operational, and financial impact of adopting the ready-to-use formulation, to support future decisions in aesthetic practice and inform a pharmacoeconomic model.

Who can participate?
Healthcare professionals (such as doctors, dentists, or nurse prescribers) working in UK aesthetic clinics who have at least three years of experience administering botulinum toxin treatments. Patients receiving treatment at these clinics will not be enrolled in the study, and no patient-identifiable data will be collected.

What does the study involve?
Clinics taking part will be provided with 10 vials of RelabotulinumtoxinA to use in the normal course of their practice. Participating clinicians will complete three questionnaires: one before they begin using the product, one after one month, and one at six months. The questionnaires ask about their experience using the product, including ease of use, impact on workflow, patient satisfaction (as observed by the clinician), and financial or operational considerations. No extra procedures or clinic visits are required for patients, and data will be anonymised.

What are the possible benefits and risks of participating?
There are no direct risks to clinicians participating in the study. Clinics benefit from the

opportunity to evaluate a new botulinum toxin formulation in routine practice and contribute to research that may influence future guidance in aesthetic medicine. Patients are not involved as study participants and receive standard treatment as part of normal care.

Where is the study run from?
The study is sponsored by Galderma UK Ltd and run in collaboration with Medialis Ltd, and will involve 30 private aesthetic clinics across the UK, including England, Wales, Scotland and Northern Ireland.

When is the study starting and how long is it expected to run for?
September 2024 to March 2026

Who is funding the study?
Galderma UK Ltd

Who is the main contact?
Dr. Wojciech Konczalik, wojciech.konczalik@galderma.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Mr Wojciech Konczalik

Contact details
Evergreen House North
Grafton Place
London
United Kingdom
NW1 2DX
+44 (0)7917650496
wojciech.konczalik@galderma.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
355065

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
PURE-QUEST: preliminary UK RelabotulinumtoxinA experience – a questionnaire-based observational real-world study evaluating clinician experiences with a ready-to-use botulinum toxin (RelabotulinumtoxinA) in aesthetic practice

Acronym
PURE-QUEST

Study objectives
This study is being conducted to gather real-world insights from healthcare professionals on the use of RelabotulinumtoxinA, a new ready-to-use botulinum toxin, in routine aesthetic practice. It aims to evaluate the product's ease of use, impact on clinic workflow, and clinician perceptions of patient outcomes, while also exploring its pharmacoeconomic implications for aesthetic clinics.

Ethics approval required
Ethics approval not required

Ethics approval(s)
The Health Research Authority reviewed the manuscript on IRAS and agreed that the study constitutes post-marketing surveillance with no direct engagement of patients and therefore does not require REC approval

Study design
Observational questionnaire-based study

Primary study design
Observational

Secondary study design
Questionnaire-based study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Facial lines, specifically glabellar (frown) lines and lateral canthal (crow's feet) lines

Interventions
The study will recruit healthcare professionals from UK aesthetic clinics who will use RelabotulinumtoxinA as part of their routine practice to treat patients seeking botulinum toxin for facial lines. Participating clinicians will complete structured questionnaires at baseline, 1 and

6 months to capture their experiences with the product, including ease of use, patient satisfaction, and clinic workflow impact. Data will be anonymised and analysed descriptively to provide real-world insights and explore the pharmacoeconomic implications of the product.

Intervention Type
Other

Primary outcome measure
Clinician perception of RelabotulinumtoxinA as a convenient, ready-to-use neuromodulator with long-lasting efficacy in patients seeking aesthetic treatment. This is assessed through a single validated questionnaire item completed at baseline (prior to the first use of the product) and at 6 months following product adoption.

Secondary outcome measures
1. Clinician perception of the ease of use of RelabotulinumtoxinA, measured using a structured questionnaire at 1 and 6 months
2. Clinician perception of the potential for dosing errors or wastage when using RelabotulinumtoxinA, measured using a structured questionnaire at 1 and 6 months
3. Clinician perception of patient satisfaction with treatment outcomes (as observed in their practice), measured using a structured questionnaire at 1 and 6 months
4. Clinician perception of the need for treatment touch-ups or adjustments after initial injection, measured using a structured questionnaire at 1 and 6 months
5. Clinician perception of the financial impact of using RelabotulinumtoxinA on clinic operations (e.g., efficiency, cost-effectiveness, revenue), measured using a structured questionnaire at 1 and 6 months
6. Clinician perception of the impact of RelabotulinumtoxinA on clinic reputation and patient retention, measured using a structured questionnaire at 1 and 6 months
7. Clinician perception of sustainability and reduction in clinical waste associated with using a ready-to-use formulation, measured using a structured questionnaire at 1 and 6 months

Overall study start date
01/09/2024

Completion date
15/03/2026

Eligibility

Key inclusion criteria
1. UK-registered aesthetic clinics that offer botulinum toxin treatments as part of their routine practice
2. Clinics with at least one licensed healthcare professional (HCP) qualified to prescribe and administer botulinum toxin treatments, including doctors, dentists, or nurse prescribers
3. The prescribing healthcare professional must have a minimum of 3 years’ experience in administering botulinum toxin for aesthetic indications
4. Clinics that have the necessary facilities to store botulinum toxin safely, including refrigeration at 2–8°C
5. Clinics that have appropriate treatment rooms and equipment for administering botulinum toxin safely, including access to emergency equipment
6. Clinics that agree to treat a minimum of 10 eligible patients using RelabotulinumtoxinA as part of routine clinical practice within the study period

7. Clinics and participating HCPs willing to complete all three study questionnaires (baseline, 1 and 6 months)
8. Clinics and HCPs willing to adhere to the study protocol and data confidentiality requirements
9. Clinics and HCPs who provide written informed consent to participate in the study

Participant type(s)
Health professional, Other

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Clinics that do not routinely provide botulinum toxin treatments as part of their aesthetic practice
2. Clinics that do not have a prescriber on-site with appropriate qualifications to administer botulinum toxin (e.g., doctor, dentist, nurse prescriber)
3. Healthcare professionals (HCPs) with less than 3 years of experience administering botulinum toxin for aesthetic purposes
4. Clinics that lack appropriate storage facilities, such as a refrigerator capable of storing botulinum toxin at 2–8°C
5. Clinics that do not have appropriate treatment facilities and emergency equipment necessary for the safe administration of botulinum toxin
6. Clinics or healthcare professionals unable or unwilling to recruit 10 suitable patients for botulinum toxin treatment within the study timeframe
7. Healthcare professionals unwilling or unable to complete all three required study questionnaires (baseline, 1 and 6 months)
8. Clinics or healthcare professionals who refuse to comply with the study protocol, data confidentiality, and GDPR requirements
9. Clinics and healthcare professionals directly employed by Galderma UK Ltd, or otherwise involved in the design and oversight of the study, to avoid potential conflicts of interest

Date of first enrolment
01/05/2025

Date of final enrolment
01/07/2025

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Not provided at time of registration
United Kingdom
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Sponsor information

Organisation
Galderma (UK) Limited

Sponsor details
Evergreen House North
Grafton Place
London
England
United Kingdom
NW1 2DX
+44 (0)7827251766
medinfo.uk@galderma.com

Sponsor type
Industry

Website
https://www.galderma.com/uk/contact-us

Funder(s)

Funder type
Industry

Funder Name
Galderma (UK) Limited

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/09/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication