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Long-term effects of the liquid neuromodulator Alluzience® on ageing

Submission date
22/10/2023

Recruitment status
No longer recruiting

Registration date
11/12/2023

Overall study status
Ongoing

Last Edited
22/11/2023

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Alluzience® is a commercially available form of botulinum toxin. Coined as the 'first liquid toxin', it comes in a ready to use solution and does not require reconstitution like other brands. This study assesses the long term effectiveness of Alluzience® on the presence of glabellar lines and crow's feet and the impact upon patient perceptions of body image, psychological wellbeing, physical health and interpersonal communications.

Who can take part?
We will recruit 3-5 pairs of identical twins over the age of 21 years.

What does the study involve?
Twins will be assessed for clinical suitability and if suitable, one twin will be given Alluzience® treatment for upper face, whilst the other twin will be observed for the duration of the study. Treatment will be offered after consultation, consent and photographs are taken. All information and photography is for medical records and will not be used for social media or websites. Most treatments will take place at 10 Argyll Street, W1F 7TQ. The treated twin will receive repeated treatments every 4-6 months for 5 years. At each appointment, new photographs will be taken and a patient perceptions questionnaire filled out. Each appointment will last approximately 1 hour. The other twin will not receive Alluzience® and will be asked to abstain from any botulinum toxin treatment for upper face wrinkles for the duration of the study. They will be asked to attend a short appointment once a year to have photographs taken, and receive a questionnaire.

What are the possible benefits and risks of participating?
Benefits of participation
- Contribution to scientific literature
- Treated patients will receive botulinum toxin treatment to hyperfunctional glabellar lines and crow's feet
Risks of participation
Side effects of Alluzience® as per manufacturers guidance: Injection site reactions (including pain, itching, bruising, swelling, redness) and headache have been the most commonly reported side effects following the use of Alluzience® for the treatment of glabellar lines. Other

reported side effects are eye ptosis (drooping of the upper eyelid), visual impairment/diplopia (double vision), dry eye, eye watering, reduced blinking, photophobia (increased light sensitivity), sensation of pressure, eye strain, reduction in facial expression, asymmetry, nausea and dizziness. Most of these events are mild or moderate in intensity.. Alluzience® belongs in a class of BoNT-A. Life threatening difficulties in swallowing and breathing have been reported following treatment with a BoNT-A toxin, along with reports of death (although not reported in any patients receiving treatment for glabellar lines). People who already have swallowing or breathing problems before receiving Alluzience® may have the highest risk of getting these problems. These problems can happen within hours, or days to weeks after an injection of a BoNT-A toxin, usually because the muscles used to breathe and to swallow can become weak after the injection. Swallowing problems may last for several weeks. People who cannot swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with a BoNT-A toxin.
Alluzience® belongs to a class of BoNT-A products where hypersensitivity have rarely been reported. Alluzience® should not be administered to individuals with known hypersensitivity to BoNT-A or any ingredient in the formulation. Anaphylactic or allergic reactions may range from mild, such as a skin rash, to severe. Severe or serious allergic reactions may include, but are not limited to, the following:
Trouble breathing
Swelling of the skin, mouth, or tongue
Hives on the skin
Itchiness of the skin
Feeling lightheaded, dizzy, or like you are going to faint
Persistent stomach pain, throwing up, or loss of bladder or bowel control
Death in some instances

In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms which are often seen in patients with a serious condition called botulism.
These symptoms include:
loss of strength and muscle weakness all over the body
double vision
blurred vision and drooping eyelids
hoarseness or change or loss of voice (dysphonia)
trouble saying words clearly (dysarthria)
loss of bladder control
trouble breathing
trouble swallowing

Where is the study run from?
Acquisition Aesthetics (UK)

When is the study starting and how long is it expected to run from?
September 2023 to October 2029

Who is funding the study?
Acquisition Aesthetics (UK)

Who is the main contact?
Ayushi Gupta, research@acquisitionaesthetics.co.uk
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Long-term effects of a liquid neuromodulating agent, Alluzience®, for the reduction of upper facial rhytdies and perceptions of age, health and wellbeing

Study objectives
1. Repeated treatments of Alluzience® will prevent the formation or reduce the visibility of glabellar (frown) lines and crow's feet (lateral canthal lines), measured by the Global Aesthetic Improvement Scale (GAIS).
2. Perceptions of body image, psychological wellbeing and interpersonal communications will be improved for treated individuals.

Ethics approval required
Ethics approval not required

Ethics approval(s)
Independent opinion is currently being sought.

It is unlikely to be required as a non-NHS study which is not a Phase 1 study, does not include adults unable to consent for themselves requiring approval under the Mental Capacity Act (in England and Wales) or the Adults with Incapacity Act (Scotland), and does not involve human tissue.

Study design
Multi-centre prospective interventional twin study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Dental clinic, Medical and other records, Other therapist office, Telephone, Training facility /simulation

Study type(s)
Prevention, Quality of life, Treatment, Efficacy

Participant information sheet
To follow

Health condition(s) or problem(s) studied
Treatment and prevention of upper facial rhytdies including glabellar frown lines and crow’s feet.

Interventions
One twin will be treated with Alluzience® and one will not treated. There will be no blinding of either patients or clinicians; twins will be allowed to decide which of them receives treatment and which is the control. This will be a multi-centre study with repeated intervention (every 4-6 months) and follow up over a period of up to 5 years.

Patients will self-allocate to the treatment or no treatment arm of the trial. Treated patients will be assessed for clinical suitability at an initial consultation. The treatment dose is 110 Speywood Units of Alluzience (ready to use Abo-BoNT-A solution) divided into 5 injection sites across the glabella and 3 across the crow's feet, bilaterally. A total of 11 injections are therefore administered subcutaneously or intramuscularly via needle. Treatment will be recommended every 4-6 months (and no more frequently than every 3 months) for 5 years based on clinical need. Untreated patients will not receive a placebo. The treated group will have before and after photos taken at each treatment appointment, while the untreated group will have photos taken once a year, and these will be assessed by aesthetic experts according to the Global Aesthetic Improvement Scale (GAIS). Both treatment groups will complete a questionnaire to determine psychological well-being once a year.

Intervention Type
Procedure/Surgery

Primary outcome measure

Assessed annually up to 5 years:
1. Assessor reported outcomes: improvement in Global Aesthetic Improvement Scale (GAIS) ratings following repeated treatments with Alluzience®
2. Patient reported outcomes: improvement in Global Aesthetic Improvement Scale (GAIS) ratings following repeated treatments with Alluzience®

Secondary outcome measures
Assessment of patients' emotional display, feelings about self, interpersonal communications and well-being (physical and psychological). This is undertaken via patient self-assessment questionnaires. Assessed annually up to 5 years.

Overall study start date
01/09/2023

Completion date
01/10/2029

Eligibility

Key inclusion criteria
1. Over the age of 21 years
2. Male or female
3. Identical twin; both twins must consent to participation in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
21 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
10 (5 sets of identical twins)

Key exclusion criteria
1. Pregnant or breastfeeding
2. Previous treatment with permanent/non-biodegradeable products to the upper face area. I.e. lifting threads or fat transfer (lipofilling)
3. Significant trauma and/ or surgery to upper face including fracture of skull/facial bones
4. Significant scarring of upper face
5. Neuromuscular disorder of the upper face including significant nerve palsy

6. Prescribed anticoagulant or have a bleeding disorder
7. Current or previous psychiatric illness (e.g. Psychosis, depression, anxiety) that could affect safety during the study
8. Participating in another scientific study within 30 days of starting treatment
9. Twins must not be receiving any other neuromodulator treatment for the reduction of upper facial rhytdies for the duration of the study

Date of first enrolment
01/10/2023

Date of final enrolment
01/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Acquisition Aesthetics
10 Argyll Street
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Sponsor information

Organisation
Acquisition Aesthetics

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Sponsor type
Industry

Website

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Funder(s)

Funder type
Industry

Funder Name
Acquisition Aesthetics

Results and Publications

Publication and dissemination plan
We aim to publish the 2 and 5 year results in a high-impact peer-reviewed journal.

Intention to publish date
01/01/2030

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available on request from Ayushi Gupta - research@acquisitionaesthetics.co.uk

IPD sharing plan summary
Available on request