

Evaluation of the efficacy of intradermal onabotulinumtoxinA for the treatment of accordion (cheek) wrinkles: A 2-centre randomized double-blinded split face clinical trial

ACTRN12614000196640

Status	RECRUITING
Phase	Phase 2
Sponsor	David Ellis
Enrollment	20 participants

Plain Language Summary

This study is testing whether tiny injections of Botox (onabotulinumtoxin A) into the cheek skin can reduce the appearance of accordion-style wrinkles that appear when you smile. It is a split-face trial, meaning one side of the face gets the real treatment and the other side gets a placebo, so each person acts as their own comparison. Researchers will measure wrinkle improvement, skin elasticity, and patient satisfaction.

You may be eligible if:

- You are between 40 and 75 years old
- You have visible cheek (accordion) wrinkles you want treated
- Your wrinkles are at least grade 1 at rest or when smiling widely
- You are mentally able to give your own consent
- You are able to attend follow-up appointments for the duration of the study
- If you take low-dose aspirin (81 mg), you are willing to stop it two weeks before the trial

You may NOT be eligible if:

- You are pregnant or breastfeeding
- You have previously had Botox injections in your cheeks
- You have had an allergic reaction to botulinum toxin before
- You have had ablative laser treatment on your cheeks
- You have had non-ablative laser treatment on your cheeks in the last 6 months
- You have had surgery in your cheek area
- You have a muscle or nerve disease such as myasthenia gravis or ALS

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (6)

- All male and female patients between ages of 40 - 75 complaining of accordion wrinkles and keen for intervention only for the accordion wrinkles.
- Accordion wrinkles of at least grade 1 at rest and/or on extreme smile.
- Of sound mind and able to give consent.
- Able to be followed up for duration of study.
- Patients can have been their crow's feet or squint lines treated anytime prior to start of trial. (Different sets of muscles involved and the location of our injections is of adequate distance from squint lines hence will not affect the outcome)

... and 1 more (see full listing online)

Exclusion (7)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12614000196640>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at anzctr.org.au. Generated by ClinicalTrialsFinder.org.

- Females who are pregnant or breast-feeding.
 - Patients who have previous botulinum toxin A injections at the cheek area.
 - Patients who have previous allergy to botulinum toxin A.
 - Patients with previous ablative laser procedures in the cheek area.
 - Patients with non-ablative laser treatment in cheek area in the last 6 months.
- ... and 2 more (see full listing online)

Locations (1 total)

Ontario, Canada