



740-747-6427

Study Summary of Glabella (GL) Phase 2 Investigational Study with quick onset botulinum toxin (trenibotulinumtoxin E) mixed with Botox 04OCT26

- For full study details, please review the informed consent form.
- 5 month study with 14 visits. At every visit, photographs of the GL area will be taken, patient will answer questions on an iPad, doctor will assess your GL area, a physical exam will be performed, vital signs will be taken, and questions about changes in health will be asked.
 1. **Visit 1:** Screening visit to see if you are eligible for the study: This entails activities such as a physical examination, EKG, bloodwork, photographs, questionnaires. Visit 2 must be within 2 weeks of Visit .
 2. **Visit 2:** Baseline visit (Day 1 of study) 5 standard GL injections of study drug
 3. **Visit 3:** A second visit 7-9 Hours after the injections on Day 1
 4. **Visit 4:** Day 2/ 24 hours after the injection
 5. **Visit 5:** Day 3/ 48 hours after the injection
 6. **Visit 6:** Day 5
 7. **Visit 7:** Day 7: **EKG, Labs**
 8. **Visit 8:** Day 14
 9. **Visit 9:** Day 21
 10. **Visit 10:** Day 30: **EKG, Labs**
 11. **Visit 11:** Day 60
 12. **Visit 12:** Day 90: **EKG, Labs**
 13. **Visit 13:** Day 120
 14. **Visit 14:** Day 150: **EKG, Labs**
- You are paid \$1400 if you complete all visits. No cost to you.
- Dose finding study with **10 different dosing possibilities**. One is standard Botox 20 Units, one is placebo and the other 8 are differing combinations of Botox and the quick onset investigational botulinumtoxin E. There is a 1 in 10 chance of receiving placebo. You have one study injection treatment on Visit 2.
- Initial screening visit may be 4 hours.

- After treatment on Visit 2, you have to wait 30 minutes after injections before leaving. This visit may take up to 3 hours. You will also need to come back 7-9 hours after injection time for another visit on that same day. So 2 visits in 1 day!!
- Most appointments besides the first two will be an hour or less; however, visits on days 7, 30, 90, and 150 will be longer visits since EKG and bloodwork will be done (up to 2 hours).
- We have tables to work at during your visit. Water and snacks are available.
- If interested in this study:
 1. visit our website at **www.nrgoh.com**
 2. text us (740-747-6427) your **name and email address** stating you are interested in this study. We will email you a copy of the informed consent form which has all the detailed information about the study.
 3. fill out the NRG medical history form and email this back to us at mhinze@nrgoh.com and jhartert@nrgoh.com with an “at rest” facial photo and a “mad face” facial photo to see if you are eligible for the study **OR** you can schedule an in-person visit and bring the filled out form to the pre-screening visit to see if you are eligible in person
- **The best way to contact us is via text:** however, **photos will not go through** our text system, so those need to be emailed.
- **There will be 3 schedule options based on your Day 2 treatment:**
 1. **Wednesday treatment start:**
 - **Visit 1: Screening.** Visit 2 must be within 2 weeks of Visit 1
 - **Visit 2: Baseline treatment:** Day 1 of study. **Wednesday afternoon.** 5 standard glabellar injections given.
 - **Visit 3:** A 2nd visit on Day 1. **Wednesday PM 7-9 hours after injections.**
 - **Visit 4:** Day 2/ 24 hours after the injection. **Thursday afternoon**
 - **Visit 5:** Day 3/ 48 hours after the injection. **Friday afternoon**
 - **Visit 6:** Day 5. **Monday 4:30-9 PM**
 - **Visit 7:** Day 7 **Wednesday afternoon:** EKG, Labs
 - **Visit 8:** Day 14 **Wed/Thurs**
 - **Visit 9:** Day 21 **Wed/Thurs**
 - **Visit 10:** Day 30 **Wed/Thurs:** EKG, Labs
 - **Visit 11:** Day 60 **Wed/Thurs/Fri**
 - **Visit 12:** Day 90 **Wed/Thurs/or Fri:** EKG, Labs
 - **Visit 13:** Day 120 **Wed/Thurs/or Fri**
 - **Visit 14:** Day 150 **Wed/Thurs/Fri:** EKG, Labs
 2. **Thursday treatment start**
 - **Visit 1: Screening.** Visit 2 must be within 2 weeks of Visit 1
 - **Visit 2: Baseline:** Day 1 of study. **Thursday AM.** 5 standard glabellar injections given.
 - **Visit 3:** A 2nd visit 7-9 Hours after the injection on Day 1. **Thursday PM.**
 - **Visit 4:** Day 2/ 24 hours after the injection. **Friday AM.**
 - **Visit 5:** Day 3/ 48 hours after the injection. **Saturday AM.**

- **Visit 6:** Day 5. **Monday 4:30-9 PM**
- **Visit 7:** Day 7 **Wednesday or Thursday:** EKG, Labs
- **Visit 8:** Day 14 **Wed/Thurs/or Fri**
- **Visit 9:** Day 21 **Wed/Thurs/or Fri**
- **Visit 10:** Day 30 **Wed/Thurs/or Fri:** EKG, Labs
- **Visit 11:** Day 60 **Wed/Thurs/or Fri**
- **Visit 12:** Day 90 **Wed/Thurs/or Fri:** EKG, Labs
- **Visit 13:** Day 120 **Wed/Thurs/or Fri**
- **Visit 14:** Day 150 **Wed/Thurs/or Fri:** EKG, Labs

3. Friday treatment start

- **Visit 1: Screening.** Visit 2 must be within 2 weeks of Visit 1
- **Visit 2: Baseline:** Day 1 of study. **Friday AM.** 5 standard glabellar injections given.
- **Visit 3:** A 2nd visit 7-9 Hours after the injection on Day 1. **Friday PM**
- **Visit 4:** Day 2/ 24 hours after the injection. **Saturday AM**
- **Visit 5:** Day 3/ 48 hours after the injection. **Sunday AM**
- **Visit 6:** Day 5. **Wednesday** (or Monday 4:30-9)
- **Visit 7:** Day 7 **Wed/Thurs/or Fri:** EKG, Labs
- **Visit 8:** Day 14 **Wed/Thurs/or Fri**
- **Visit 9:** Day 21 **Wed/Thurs/or Fri**
- **Visit 10:** Day 30 **Wed/Thurs/or Fri:** EKG, Labs
- **Visit 11:** Day 60 **Wed/Thurs/or Fri**
- **Visit 12:** Day 90 **Wed/Thurs/or Fri:** EKG, Labs
- **Visit 13:** Day 120 **Wed/Thurs/or Fri**
- **Visit 14:** Day 150 **Wed/Thurs/or Fri:** EKG, Labs