



Clinical trial investigating IncobotulinumtoxinA, a new treatment for Pelvic Floor Muscle Dysfunction

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What/How?

IncobotulinumtoxinA is an approved injected medication for several conditions that involve muscle overactivity, but its use for vulvar pain (vulvodynia) is experimental. This is a research study to learn whether this drug can **safely and effectively reduce vulvar pain** in people with **provoked vestibular pain** that may be caused by tight pelvic floor muscles.

The study will include **5 visits over 26-30 weeks**, including the following:

- **2-week** screening period
- **12-week** treatment phase with 2 injection/treatment visits and 2 follow-up visits

Participants will initially be **randomly assigned** to receive either IncobotulinumtoxinA or placebo injections. The placebo injection does not contain any active medication. However, those women who initially received placebo will **later be given the opportunity to receive the study medication at no cost** while being monitored by the study physician.

This trial is **only taking place at our offices in NY and DC**. There are no other locations that are offering the ability to participate in this study.

Who?

- Female participants **≥18 years of age** who are premenopausal
- Have **pelvic floor muscle pain for at least 3 months** and for no more than 15 years
- Have **not received injections of botulinum toxin** (Botox, Dysport, Jeuveau, or Xeomin) **in the pelvic floor muscles** within the last **12 months** prior to starting study
- Are willing to attend all study visits and feel comfortable receiving **2 rounds** of injections with our office

EMAIL US IF INTEREST IN JOINING
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