

## How long will I participate?

12 months after treatment starts.

## Will I be compensated?

All clinic visits for both mirabegron, vibegron, and Botox A® go through your normal clinical care and your health insurance.

You will be paid up to \$425 for your participation: \$50 at baseline, \$125 at the start of treatment, \$100 at your 3-month visit, and \$50 each at your 6, 9, and 12 month visits, which take place over the phone.

## What do I have to do?

If you are interested, you will be evaluated at treated in the UC San Diego Women's Pelvic Medicine Center for your UUI. If the study team determines you are eligible and you want to participate, you will be randomized (like the flip of a coin) to one of two treatment groups (Beta 3 Agonist medication or Botox A®).



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A RESEARCH STUDY BEING CONDUCTED BY

## UC San Diego Health

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# UC San Diego Health



## Therapy for Urgency Urinary Incontinence: "BEST" RESEARCH STUDY

Beta-Agonist Medication vs.  
Botox A®



## What is Urgency Urinary Incontinence (UUI)?

A sudden, strong urge to urinate that is hard to stop is called Urgency Urinary Incontinence (UUI). Women with this type of incontinence may leak urine on the way to the bathroom. Some women can also have urinary frequency and nighttime problems. It is a common condition that can have a negative effect on a woman's quality of life.

## What are the treatment options for UUI?

- Behavioral therapy
- Medications
- Onabotulinumtoxin A injection (Botox A®)
- Nerve Stimulation

## What is this trial about?

This study compares beta agonist oral medication (mirabegron or vibegron) to Botox A® (an injected medication). Both treatments have been shown to help UUI, but they have not yet been directly compared to each other to see which treatment is better for which patient. That is the goal of this study.

### • **Mirabegron and Vibegron:**

- FDA approved treatments
- Prescription medication taken by mouth once a day
- Lessens UUI by relaxing the bladder muscle

### • **Onabotulinumtoxin A (Botox A®)**

- FDA approved treatment
- Injected into the bladder in office
- Lessens UUI by decreasing bladder contractions

## How many people will take part in this study?

432 women across 5 states in the U.S. will be asked to participate. Around 87 women will be patients from US San Diego and throughout San Diego communities.

### Participating sites:

- Howard University, Washington, DC
- University of Alabama, Birmingham, AL
- University of California San Diego, San Diego, CA
- University of New Mexico, Albuquerque, NM
- Women & Infants Hospital of Rhode Island, Providence, RI



### Study population:

- >18 years old with UUI
- Do not plan to become pregnant during the study (12-month duration)
- Have tried anticholinergic medication in the past without improvement, like Ditropan® or Detrol®

### You cannot participate if you are/have:

- Unable to take mirabegron, vibegron, or Botox A®
- Had prior use of mirabegron, vibegron, or Botox A®
- Blood in urine that has not been evaluated
- Current or prior bladder cancer
- History of radiation to your pelvis
- Vaginal prolapse (bulge)

