

4. **Urinary Incontinence, 2012 *NEJM*.** Urgency urinary incontinence is characterized by unpredictable loss of urine; it is a prevalent condition that occurs disproportionately in women, affecting up to 19% of older women in the United States. Duke researchers conducted a randomized trial comparing an oral drug regimen with a single botox injection into bladder muscle to assess the reduction in episodes of urgency urinary incontinence over the course of 6 months, improvement in quality of life, and side effects. Patients were randomly assigned to the drug or botox in a 1:1 ratio. Of 249 women who underwent randomization, 247 were treated, and 241 had data available for the primary outcome analyses. The mean reduction in episodes of urgency urinary incontinence per day over the course of 6 months, from a baseline average of 5.0 per day, was 3.4 in the drug group and 3.3 in the botox group ($P=0.81$). Complete resolution of urgency urinary incontinence was reported by 13% and 27% of the women, respectively ($P=0.003$). Quality of life improved in both groups, without significant between-group differences. The drug group had a higher rate of dry mouth (46% vs. 31%, $P=0.02$) but lower rates of catheter use at 2 months (0% vs. 5%, $P=0.01$) and urinary tract infections (13% vs. 33%, $P<0.001$).

- (a) How many hypothesis tests are described in these results?
- (b) Consider the outcome of mean reduction in episodes of urgency urinary incontinence per day over the course of 6 months.
 - i. What are the null and alternative hypotheses?
 - ii. How do you think they tested the null hypothesis?
 - iii. How do you interpret their results?
- (c) Consider the outcome of complete resolution of urgency urinary incontinence.
 - i. What are the null and alternative hypotheses?
 - ii. How do you think they tested the null hypothesis?
 - iii. How do you interpret their results?