

# **Bathing In the Bed-bound Nursing Home Elderly**

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## **LAY ABSTRACT**

### **STUDY PURPOSE**

Urinary tract infection (UTI) is the most common infection in nursing home care residents. While these infections are a result of many different factors, bacteria from stool/feces might be a possible source for these infections, especially in patients who wear diapers. As such, keeping these patients clean is extremely important. Currently there are two forms of washing/bathing being used on this population. The first is bathing at the bedside with a basin of water (usually approximately 3 liters) and soap. The second is a more elaborate shower/bath in a bathing chair which involves the use of much more water. Currently no studies have been conducted to assess whether the method of bathing affects the rate of urinary tract infection in this population. We suspect that patients who are undergo high volume bathing will have less urinary tract infection than those bathed by hand at the bedside.

### **STUDY SUBJECTS AND METHOD OF RECRUITMENT**

325 bed-bound nursing home residents will be randomized to each arm. These patients will be recruited from the nursing home patient list. They will be contacted in person by a member of the study team. If they are unable to understand what the study entails, the patients health care proxy/research proxy will be contacted by the member of the study team prior to enrollment.

### **STUDY PROCEDURE:**

The patient's will be bathed three times per week in either of the two bathing methods. Each of the subjects will be seen daily by a study representative who will record any evidence of UTI—symptoms, fever, increased confusion etc. If any of these signs exist, a urinalysis (examination of the subject's urine) will be sent.

### **ISSUES:**

None

### A. Study Design and Statistical Analysis

Bed bound nursing home patients wearing diapers, with no indwelling urinary catheter will be randomized to either conventional hand bathing by nurses aids versus high volume water bathing/seated shower bathing.

325 bed-bound nursing home residents will be allotted to each arm. This is based upon a theorized UTI incidence of 16% and an expected 50% reduction in the primary outcome (8%). Unpaired t-test was used to calculate study size.

Patient will be randomized in a non-blinded fashion. Prior to randomization, subjects will be stratified by age, diabetes, level of dementia, sex, neurological illness—Alzheimer's, Parkinson's, CVD-- ,history of BPI-I and prostate cancer.

There will be no crossover of the study populations.

Primary outcome of UTI. will be assessed in both arms and compared via chi-squared analysis.

### B. Study Procedure

Subjects will be randomized to either of the following bathing procedures: 1) Subjects to be bathed by a team of two nurses/nurses aids with standard bed-side bathing procedures using sterile wash cloths and exactly 3 liters of tap water [facility will have been previously documented to have appropriately sanitary tap water system without evidence of current legionella burden]. **OR** 2) Patients will be transported to bathing room and placed in sanitized bathing chair/recliner, where they will be washed with soap and greater than 10 liters (> 7 minutes) of tap water.

Subjects from both groups will be monitored daily for symptoms of UTI—fever, new or increased burning pain on urination, flank pain or suprapubic pain, changes in character of urine, worsening mental function. Patients with any of these symptoms will have urine specimen sent for Ua/Umicro/Uculture. Any analysis of urine with evidence of bacteruria  $10 \times 10^5$  CFU/ml will be considered a positive study.

After randomization the subjects will be studied for 8 months. Each patient's involvement will be up to arrival at either the primary endpoint or the 8 month stop date.

### C. Medical Device

AS ABOVE.

1. Hand bathing kit: 3 Liters of water, soap, and new disposable washcloths.
2. Bathing chair/device being used in the nursing home of study. If without, bathing chair and safe bathing environment to be created.

### D. Study Questionnaires

None.

### E. Study Subjects

#### Inclusion/exclusion criteria for subjects

Inclusion Criteria:

1. age >65 years
2. bedbound
3. nursing home occupant.
4. Incapable of self-bathing.

Exclusion Criteria:

1. UTI within the past 2 months
2. UTI within the first 2 days of study.
3. Indwelling catheter
4. Recent prostate or bladder instrumentation (last 6 months).

Note: Elderly subjects, some of whom will be without capacity, will be involved in this study. Those unable to fully assess the risk and benefits of the study will only be involved after research proxy is involved. Those patients becoming severely agitated during the bathing process will be evaluated by medical professional and health care proxy. If either feel that the patient should be withdrawn from the study then the subject will be removed.

Consent will be obtained via health care proxy/research proxy or via the subject if he or she is deemed consentable.

#### **F. Recruitment of Subjects**

Subjects will be identified through nursing home resident census, and will be contacted by study representative. If patient is not deemed competent to consent to study, health care proxy will be identified and contacted.

#### **G. Potential Conflict of Interest**

None

#### **H. Location of the Study**

Nursing Home

#### **Potential Risks**

Increased risk of patient injury via transportation to shower room. Increased risk for legionella pneumonia due to possible increased exposure to aerosolized contaminated water supply.

#### **I. Potential Benefits**

Decreased incidence of UTI.

#### **J. Alternative Therapies**

None

#### **K. Compensation to subjects**

None