Treatment of Spinal Cord Injury Patients for Neurogenic Bladder: Anticholinergic Agent vs. Mirabegron

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RECRUITMENT STATUS: COMPLETED
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STUDY DESCRIPTION

Brief Summary
We propose to test the hypothesis that cognition will improve with substitution of mirabegron for the anticholinergic agent (AC) in elderly persons with spinal cord injury (SCI) who require neurogenic bladder (NGB) treatment.

Condition or Disease: Spinal Cord Injuries
Neurogenic Bladder
Cognitive Change

Intervention/treatment: Drug: Mirabegron
Phase: Early Phase 1

DETAILED DESCRIPTION

The strong evidence for detrimental effects of AC agents on cognition, led the American Urological Association to update its guidelines in 2015 to include mirabegron as an alternative first-line agent for treatment of overactive bladder (OAB). NGB symptoms are very similar to OAB so the conditions are often treated similarly; however, data is lacking on the use of this promising agent for NGB. We thus propose to test the hypothesis that cognition will improve with substitution of mirabegron for the AC agent in elderly persons with SCI who require NGB treatment.

Subjects eligible for enrollment will have been treated with an AC agent for at least 3 months prior to enrollment. Baseline measurements will be recorded for subjects currently treated with an AC agent, after enrollment, the subject will start treatment with the study drug. Measurements from baseline (AC agent) will be compared to measurements taken after study intervention (mirabegron).

STUDY DESIGN

Study Type: Interventional
Estimated Enrollment: 20 participants
Intervention Model: Single Group Assignment
Masking: None (Open Label)
Primary Purpose: Treatment
Official Title: Treatment of Spinal Cord Injury Patients for Neurogenic Bladder: Anticholinergic Agent vs. Mirabegron

Actual Study Start Date: December 2018
Actual Primary Completion Date: March 2020
Actual Study Completion Date: March 2021

ARMS AND INTERVENTIONS

Arm Intervention/treatment
Other: Neurogenic Bladder
Spinal Cord Injury patients with known neurogenic bladder on treatment with Anticholinergic Agents at baseline switched to mirabegron as the study intervention
Drug: Mirabegron
Beta-3 adenoreceptor agonist

OUTCOME MEASURES

Primary Outcome Measures: 1. Change in cognitive measure - Logical Memory I (Immediate) - baseline and post treatment with mirabegron [ Time Frame: Change from Week 0 to Week 26 ]
2. Change in cognitive measure of memory (SLUMS) - baseline and post treatment with mirabegron [ Time Frame: Change from Week 0 to Week 26 ]
3. Change in cognitive measure of executive function (Stroop test) - baseline and post treatment with mirabegron [ Time Frame: Change from Week 0 to Week 26 ]
4. Change in memory and executive function (TEXAS) - baseline and post treatment with mirabegron [ Time Frame: Change from Week 0 to Week 26 ]
5. Change in Neurogenic Bladder Symptom Score (NBSS) - baseline and post treatment with mirabegron [ Time Frame: Change from Week 0 to Week 26 ]
6. Change in Neurogenic Bowel Dysfunction Score (NBD) - baseline and post treatment with mirabegron [ Time Frame: Change from Week 0 to Week 26 ]

Secondary Outcome Measures:
1. Change in cognitive measure of memory (SLUMS) - baseline and post treatment with mirabegron [ Time Frame: Change from Week 0 to Week 26 ]
2. Change in cognitive measure of executive function (Stroop test) - baseline and post treatment with mirabegron [ Time Frame: Change from Week 0 to Week 26 ]
3. Symbol Digit Modalities Test - a series of symbols to assess executive function
4. Change in memory and executive function (TEXAS) - baseline and post treatment with mirabegron [ Time Frame: Change from Week 0 to Week 26 ]
5. Texas Executive Assessment (TEXAS) - A series of short term recall measures
6. Neurogenic bladder symptom questionnaire
7. Neurogenic bowel questionnaire
ELIGIBILITY CRITERIA

Ages Eligible for Study: 60 to 99 Years (Adult, Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:
Both genders with spinal cord injury being treated for neurogenic bladder and age >60 years All ethnic groups Veterans will be enrolled to allow mailing of study medication by VA pharmacies.

Laboratory results:
Normal clinical labs for CBC (complete blood count), CMP (comprehensive metabolic panel), and UA (urinalysis) within past 6 months or repeat at screening if none. For example: HCT (hematocrit) ≥34%, GFR (glomerular filtration rate) ≥ 30 mL/min, liver enzymes (AST (aspartate aminotransferase test) < 2 x upper limit of normal, ALT (alanine aminotransferase test) < 2 x upper limit of normal, alkaline phosphatase < 2 X upper limit of normal), normal electrolytes, urinalysis and asymptomatic for UTI (urinary tract infection) Taking a minimum regimen for 3 months of anticholinergic agent.

Exclusion Criteria: Diagnosis of dementia or cognitive impairment from another condition such as TBI (traumatic brain injury), ALZ (alzheimers), Lewy body dementia or vascular dementia End stage renal disease (GFR 180, diastolic BP>110 mmHg) Renal function - exclude if serum creatinine >2x normal range Liver function - exclude if >2x normal liver enzyme levels History of, or currently active treatment for cardiac dysrhythmias, including atrial fibrillation (eg. apixaban. If subject is currently taking metoprolol they will be monitored and dose may need to be adjusted on mirabegron) Current treatment with desipramine, digoxin Active/unstable conditions: inflammatory, thyroid, autoimmune, gastrointestinal (GI), hematologic, or neoplastic disorders. Exclude subjects with clinical lab values outside the normal range (other than as specified above). Subject is considered unsuitable for the study in the opinion of the investigator for any other reason.

CONTACTS AND LOCATIONS

Contacts

United States, Texas South Texas Veterans Health Care System, Audie L. Murphy Hospital San Antonio

Sponsors and Collaborators
The University of Texas Health Science Center at San Antonio

Investigator
Principal Investigator: Michelle Trbovich, MD UT Health San Antonio and VA Spinal Cord Clinic

MORE INFORMATION

Responsible Party: The University of Texas Health Science Center at San Antonio
ClinicalTrials.gov Identifier: NCT03612401
Other Study ID Numbers: HSC20180376H
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Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No
Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No
Product Manufactured in and Exported from the U.S.: Yes