Rapid Molecular Organism Identification and Mixed Flora Antibiotic Resistance Profiling (MixAR) Prospective Study

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03931538	ACTIVE, NOT RECRUITING	APRIL 30, 2019	SEPTEMBER 30, 2019

STUDY DESCRIPTION

Brief Summary

In this protocol, investigators are examining the ability for a novel multiplex PCR assay with mixed floral antibiotic resistance profiling is safe and increases effective treatment for urinary tract infections in a urology clinic over traditional culture methods alone and decreases retreatment rates in this population.

Condition or Disease: Urinary Tract Infections
Prostatitis
Interstitial Cystitis

Intervention/treatment: Diagnostic Test: Guidance 4.0 PCR test
Diagnostic Test: Urine Culture

Phase: N/A

DETAILED DESCRIPTION

The novel multiplex real-time PCR assay with mixed floral antibiotic resistance profiling offers a higher degree of sensitivity and specificity than conventional culture methods in the identification of UTI pathogens as determined by the previous prospective comparison study. Additionally, conventional methods are often inadequate in the case of polymicrobial infections. More accurate and timely pathogen identification allows for prompt and more targeted treatment with less reliance on empiric therapy and decreased rates of antibiotic therapy changes and retreatment. This leads to more favorable patient outcomes and decreases the development of resistant organisms.

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 2500 participants

Intervention Model : Factorial Assignment

Masking: Single (Care Provider)

Primary Purpose: Diagnostic

Official Title: Urinary Tract Infection: RapID Molecular Organism Identification and Mixed Flora Antibiotic Resistance Profiling (MixAR)

Actual Study Start Date: July 2018

Estimated Primary Completion Date: February 2019

Actual Study Completion Date: October 2019

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Active Comparator: Culture and Guidance 4.0 PCR test Group Physician receives both results, gets Culture report immediately before Guidance	Diagnostic Test: Guidance 4.0 PCR test All patients will have a urine culture and Guidance 4.0 PCR test run on their urine, but physicians will receive one or the other, or both depending on the treatment arm. Diagnostic Test: Urine Culture All patients will have a urine culture and Guidance 4.0 PCR test run on their urine, but physicians will receive one or the other, or both depending on the treatment arm.
Active Comparator: Guidance 4.0 PCR test and culture group Physician receives both results, gets Guidance report immediately before culture	Diagnostic Test: Guidance 4.0 PCR test All patients will have a urine culture and Guidance 4.0 PCR test run on their urine, but physicians will receive one or the other, or both depending on the treatment arm. Diagnostic Test: Urine Culture All patients will have a urine culture and Guidance 4.0 PCR test run on their urine, but physicians will receive one or the other, or both depending on the treatment arm.
Active Comparator: Guidance 4.0 PCR test only Physician receives Guidance report only	Diagnostic Test: Guidance 4.0 PCR test All patients will have a urine culture and Guidance 4.0 PCR test run on their urine, but physicians will receive one or the other, or both depending on the treatment arm.
Active Comparator: Culture Only Physician receives only culture result	Diagnostic Test: Urine Culture All patients will have a urine culture and Guidance 4.0 PCR test run on their urine, but physicians will receive one or the other, or both depending on the treatment arm.

OUTCOME MEASURES

Primary Outcome Measures:	1. Establish Safety: composite adverse event rate [Time Frame: 7 Days] Demonstrate safety of Guidance 4.0 multiplex real-time PCR organism identification with mixed floral antibiotic resistance profiling guided treatment. Safety will be measured with a composite adverse event outcome of urosepsis, pyelonephritis, hospitalization, or the need to attend an urgent care center. The composite adverse event rate in the arm tested with Guidance 4.0 will be shown to be non-inferior to that in the arm tested with traditional urine culture. Superiority will also be tested.
Secondary Outcome Measures:	1. Number of Patients with Recurrent and Persistent Infections in Each Arm [Time Frame: 7 Days] Demonstrate non-inferiority and possibly superiority of Guidance 4.0 over traditional urine C&S with respect to the percentage of recurrent and persistent infections. Persistent is remaining infection at day 7 and recurrent infection is a person that had a second infection within 30 days that was treated with antibiotics. 2. Time to Symptom Resolution in Each Arm [Time Frame: 7 days] Demonstrate superiority of Guidance 4.0 over traditional urine C&S with respect to the time to symptom resolution as demonstrated by UTISA tool. Symptom resolution will be defined as an overall rating of no symptoms on the UTISA questionnaire.
Other Outcome Measures:	1. Physician Choice for Decision Making when Provided Both Results [Time Frame: 4 Months] • To determine which test physicians, rely upon when given the results of both traditional urine C&S vs. Guidance 4.0.

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- • Patient Informed Consent form completed
- Male and Female Subjects may participate with no predetermined quotas or ratios for gender participation.
- All patients must be ≥60 years old. For patients presenting with a diagnosis of interstitial cystitis, patients may be of any age.
- Patients must be presenting for treatment of acute UTI, complicated UTI, persistent UTI, or recurrent UTI's.
- Including prostatitis, pyelonephritis, and/or interstitial cystitis.
- Data pertaining to the times at which the specimen samples are collected and stabilized needs to be documented.
- Specimen samples obtained need to have a sufficient volume necessary to perform a urine culture and Guidance 4.0.

Exclusion Criteria:
- • Do not provide written informed Consent with HIPAA authorization form.
- Taking antibiotics for any reason other than UTI at the time of enrollment
- Patients with chronic (> 10 days) indwelling catheters
- Self-catheterized patients
- Patients with neobladders

CONTACTS AND LOCATIONS

Contacts

Locations

United States, Michigan	Comprehensive Urology	Royal Oak

Sponsors and Collaborators

Pathnostics

Comprehensive Urology-a Division of Michigan Healthcare Professionals

Investigator

MORE INFORMATION

Responsible Party :	Pathnostics
ClinicalTrials.gov Identifier :	NCT03931538
Other Study ID Numbers :	Pathnostics RapID MixAR
First Posted :	April 30, 2019
Last Update Posted :	September 30, 2019
Last Verified :	April 2019
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Product Manufactured in and Exported from the U.S.:	Yes

Keywords provided by Pathnostics:	*IC UTI*	
Additional relevant MeSH terms :	*Infection* *Urinary Tract Infections* *Cystitis*	*Cystitis, Interstitial* *Prostatitis*