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An Open-Label Study of CC-10004 for Chronic Prostatitis/Chronic Pelvic Pain Syndrom

This study has been completed.

Sponsor:
Kenneth Peters, MD

Collaborator:
Celgene Corporation

Information provided by (Responsible Party):
Kenneth Peters, MD, William Beaumont Hospitals

ClinicalTrials.gov Identifier:
NCT00701311

First received: June 18, 2008
Last updated: September 25, 2014
Last verified: September 2014
History of Changes

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Purpose

Prostatitis is the most common urologic diagnosis in men under the age of 50 and the third most common diagnosis in o
Prostatitis (CP) or Chronic Pelvic Pain Syndrome (CPPS), men have lower urinary tract symptoms, pelvic pain, sexual d
quality of life. Little is known about the cause of CP/CPPS. Likewise, no definitive therapy exists for CP/CPPS. We plan
CC-10004 in men with CP/CPPS.

Condition	Intervention	
Prostatitis Chronic Prostatitis With Chronic Pelvic Pain Syndrome	Drug: CC-10004	

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: An Open-Label Study of CC-10004 for Chronic Prostatitis/Chronic Pelvic Pain Syndrome

Resource links provided by NLM:

MedlinePlus related topics: Pelvic Pain

Drug Information available for: Apremilast

U.S. FDA Resources

Further study details as provided by William Beaumont Hospitals:

Primary Outcome Measures:

- Global Response Assessment [Time Frame: 12 weeks] [Designated as safety issue: No]

  The primary efficacy measure was a Global Response Assessment (GRA), a subject completed questionnaire that n
  overall symptoms on a 7-point scale: Markedly Improved - 7, Moderately Improved - 6, Mildly Improved - 5, Same - 4
  Moderately Worse - 2, Markedly Worse - 1. The primary outcome showing response to treatment was the number of

moderately or markedly improved on the GRA scale.

Enrollment:	21
Study Start Date:	June 2008
Study Completion Date:	March 2011
Primary Completion Date:	January 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventi
Experimental: Study Drug CC-10004 Study drug CC-10004 20mg taken orally twice a day.	Drug: CC-10004 CC-10004 20 mg per da

Detailed Description:

Prostatitis is the most common urologic diagnosis in men under the age of 50 and the third most common diagnosis in o Prostatitis (CP) or Chronic Pelvic Pain Syndrome (CPPS), men have lower urinary tract symptoms, pelvic pain, sexual d quality of life.

Little is known about the cause of CP/CPPS. Likewise, no definitive therapy exists for CP/CPPS. Unlike bacterial prostat organism can be determined, CP/CPPS is not always treated with antibiotics.

Due to the significant inflammatory nature of CP/CPPS, most prior therapies have focused on targeting the inflammation studies has shown to be an inhibitor of inflammatory mediators, and may decrease the pain experienced from CP/CPPS

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Male

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Must be male aged ≥ 18 years at time of consent
- Must understand and voluntarily sign an informed consent form
- Male subjects with at least 3 months of symptoms of CP/CPPS (pain in the pelvic area, penis, scrotum, or perineum) therapies (e.g. NSAIDS)
- Must be able to adhere to the study visit schedule and other protocol requirements
- Diagnosis of Chronic Prostatitis with a Chronic Prostatitis Symptom Index of at least 15/24
- Must meet the following laboratory criteria:
  - Hemoglobin > 9 g/dL
  - Hematocrit ≥ 27%
  - White blood cell (WBC) count ≥ 3000 /mL (≥ 3.0 X 109/L) and < 20,000/mL (< 20 X 109/L)
  - Platelets ≥ 100,000 /mL (≥ 100 X 109/L)
  - Serum creatinine ≤ 1.5 mg/dL (≤ 132.6 µmol/L)
  - Total bilirubin £ 2.0 mg/dL
  - Aspartate transaminase (AST) serum glutamic oxaloacetic transaminase (SGOT), and alanine transaminase (AL transaminase,(SGPT), < 1.5x upper limit of normal (ULN)
- Males (including those who have had a vasectomy) must agree to use barrier contraception (latex condoms) when e with female capable of becoming pregnant while on study medication and for 28 days after taking the last dose of stu

Exclusion Criteria:

- Subjects who are female.
- Subjects with a documented positive urine culture within the past three months

- Subjects with duration of symptoms less than three months
- Subjects with genital infections within the past three months
- Subjects with clinical epididymitis within the past three months
- Subjects with known active or prior genitourinary cancers including renal, ureteral, bladder or prostate
- Subjects having received prior radiation to the abdominal or pelvic area
- Subjects with known bladder or ureteral calculi
- Subjects unable to complete a voiding diary
- Subjects with neutropenia (ANC < 750/ mm3)
- Any condition, including the presence of laboratory abnormalities, which places the subject at unacceptable risk if he study or confounds the ability to interpret data from the study
- History of active Mycobacterium tuberculosis infection (any subspecies) within 3 years prior to the screening visit. Int years prior to entry must have been effectively treated.
- Positive Tuberculin skin test (Mantoux test)
- Clinically significant abnormality on the chest x-ray (CXR) at screening
- Any clinically significant abnormality on 12-lead ECG at screening
- Use of any investigational medication within 28 days prior to randomization or 5 half-lives if known (whichever is long
- History of malignancy within previous 5 years (except for treated basal-cell skin carcinoma(s) and/or fewer than 3 tre carcinomas)
- Subjects currently taking chemotherapeutic agents
- Positive human immunodeficiency virus (HIV), hepatitis B, or hepatitis C laboratory test result indicating active infect
- Subjects with known history of significant disease as determined by the PI

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provide information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00701311

Locations

United States, Michigan

William Beaumont Hospital
Royal Oak, Michigan, United States, 48073

Sponsors and Collaborators

Kenneth Peters, MD

Celgene Corporation

Investigators

Principal Investigator: Kenneth Peters, MD William Beaumont Hospitals

More Information

Responsible Party:	Kenneth Peters, MD, Principal Investigator, William Beaumont Hospitals
ClinicalTrials.gov Identifier:	NCT00701311 History of Changes
Other Study ID Numbers:	2007-135
Study First Received:	June 18, 2008
Results First Received:	December 19, 2013

Last Updated: September 25, 2014
Health Authority: United States: Food and Drug Administration

Keywords provided by William Beaumont Hospitals:
Prostatitis
Pelvic pain

Additional relevant MeSH terms:

Syndrome
Somatoform Disorders
Pelvic Pain
Prostatitis
Chronic Disease
Disease
Pathologic Processes
Mental Disorders
Pain
Neurologic Manifestations
Signs and Symptoms
Prostatic Diseases
Genital Diseases, Male
Disease Attributes
Apremilast
Thalidomide
Anti-Inflammatory Agents, Non-Steroidal
Analgesics, Non-Narcotic
Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Anti-Inflammatory Agents
Antirheumatic Agents
Immunosuppressive Agents
Immunologic Factors
Leprostatic Agents
Anti-Bacterial Agents
Anti-Infective Agents
Angiogenesis Inhibitors

ClinicalTrials.gov processed this record on August 01, 2016