A Prospective, Interventional Approach to Measure Adherence in Chronic Hepatitis C Patients
Utilizing a Pilot Electronic, Monitoring Device
Kimberly Kaminski, PharmD, Brett Hensley, PharmD, Michael Toscani, PharmD, Kathleen Casey, MD, Victor M. Johnson, MA, Sara Chaudhry, PharmD, MPH

Rutgers Institute for Pharmaceutical Industry Fellowships, Ernest Mario School of Pharmacy, Piscataway, NJ

Background

Hepatitis C and Adherence

- Hepatitis C virus (HCV) is the most common chronic blood-borne infectious disease in the United States.
- The Centers for Disease Control and Prevention estimated that 2.7-3.9 million Americans were living with hepatitis C infections.1

Methods

Methods (continued)

- Objective: Determine if the use of the CleverCap® along with healthcare provider support impacts CHC patients’ adherence rates

- Secondary Objectives

  - Assess clinical, virologic, and histologic changes
  - Assess adherence rates to Peg-IFN therapy
  - Assess patient quality of life measurements

- Study Design

  - Randomized, on-dose study
  - Divided into two groups: A and B
  - A:的妻子, Peg-IFN therapy
  - B:的妻子, Peg-IFN therapy

- Enrollment

  - Patients over the age of 18 years
  - A wives, Peg-IFN therapy
  - B wives, Peg-IFN therapy

- Exclusion Criteria

  - Age > 18 years old
  - Unable to demonstrate proper use of CleverCap™

- Statistical Analysis

  - Adherence rates in CHC patients will be measured by electronic device and self-report.

  - The CleverCap™ is a novel device that aims to provide a risk management solution in conjunction with clinical trials for improved medication adherence.

  - The device attaches to a standard 30 or 60 dram vial and dispenses proper medication dosages, dispenses complete-dosage

  - The CleverCap™ triggers sound and visual notifications that remind the patient to take his/her medication

  - The device is equipped with sensors that provide the data and time stamp of when each dose was taken, and the information is wirelessly transmitted in real time to a database.

  - This functionality aids in determining and assessing a patient’s adherence and enabling real-time treatment interventions such as phone call or text messaging reminders.

  - Primary Objective

    - Determine if the use of the CleverCap® along with healthcare provider support impacts CHC patients’ adherence rates

  - Secondary Objectives

    - Assess clinical, virologic, and histologic changes
    - Assess adherence rates to Peg-IFN therapy
    - Assess patient quality of life measurements

  - Study Design

    - Randomized, on-dose study
    - Divided into two groups: A and B
    - A: Peg-IFN therapy
    - B: Peg-IFN therapy

  - Enrollment

    - Patients over the age of 18 years
    - A: Peg-IFN therapy
    - B: Peg-IFN therapy

  - Exclusion Criteria

    - Age > 18 years old
    - Unable to demonstrate proper use of CleverCap™

  - Statistical Analysis

    - Adherence rates in CHC patients will be measured by electronic device and self-report.

    - The CleverCap™ is a novel device that aims to provide a risk management solution in conjunction with clinical trials for improved medication adherence.

    - The device attaches to a standard 30 or 60 dram vial and dispenses proper medication dosages, dispenses complete-dosage

    - The CleverCap™ triggers sound and visual notifications that remind the patient to take his/her medication

    - The device is equipped with sensors that provide the data and time stamp of when each dose was taken, and the information is wirelessly transmitted in real time to a database.

    - This functionality aids in determining and assessing a patient’s adherence and enabling real-time treatment interventions such as phone call or text messaging reminders.

- Methods

  - Primary Objective

    - Determine if the use of the CleverCap® along with healthcare provider support impacts CHC patients’ adherence rates

  - Secondary Objectives

    - Assess clinical, virologic, and histologic changes
    - Assess adherence rates to Peg-IFN therapy
    - Assess patient quality of life measurements

  - Study Design

    - Randomized, on-dose study
    - Divided into two groups: A and B
    - A: Peg-IFN therapy
    - B: Peg-IFN therapy

  - Enrollment

    - Patients over the age of 18 years
    - A: Peg-IFN therapy
    - B: Peg-IFN therapy

  - Exclusion Criteria

    - Age > 18 years old
    - Unable to demonstrate proper use of CleverCap™

  - Statistical Analysis

    - Adherence rates in CHC patients will be measured by electronic device and self-report.

    - The CleverCap™ is a novel device that aims to provide a risk management solution in conjunction with clinical trials for improved medication adherence.

    - The device attaches to a standard 30 or 60 dram vial and dispenses proper medication dosages, dispenses complete-dosage