

# **Efficacy Evaluation of EASE-123 on Acute Withdrawal Syndrome and Protracted Withdrawal Syndrome of Heroin Dependence**

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## **ABSTRACT**

### **Purpose**

To evaluate the efficacy and adverse effect of functional food EASE-123 on patients with acute withdrawal syndrome and protracted withdrawal syndrome of heroin dependence.

### **Methods**

Conduct randomized, double-blind, controlled trial allocating 47 subjects into A and B groups. Subjects were provided with either EASE-123 or placebo for 7 consecutive days. Group A, 24 subjects, took functional food EASE-123; Group B, 23 subjects, took a placebo made from rice flour. Before the treatment and after the treatment, on days 1, 2, 3, 4, 5, 6, 7, and 8, the efficacy of functional food on acute withdrawal syndrome was evaluated by the overall acute withdrawal syndrome score, individual acute withdrawal symptom score, and HAMA score. The efficacy of functional food on protracted withdrawal syndrome was evaluated by overall protracted withdrawal syndrome score and individual protracted withdrawal symptom score on days 8, 15, 28, and 42.

### **Results**

1. The efficacy of EASE-123 on relieving the overall acute withdrawal syndrome, individual withdrawal symptom score, and anxiety caused by heroin termination reached a significant difference, as compared to the placebo group.
2. The efficacy of EASE-123 on relieving the overall protracted withdrawal syndrome and individual withdrawal symptom score reached a significant difference, as compared to the placebo group.
3. Tests found that EASE-123 did not affect hepatorenal functioning; no study drug related adverse effect was found and the study drug dependence was lower.

### **Conclusions**

During the whole study process of 7 EASE-123 treatment days and 42 observation days, it was found that EASE-123 was a safe treatment without adverse effects. The study drug significantly diminished the symptoms of acute withdrawal syndrome of heroin dependence, including tears, abdominal pain, diarrhea, insomnia, musculoskeletal soreness, anxiety, depression, and desires. The symptoms of protracted withdrawal syndrome, such as sleep, physical discomfort, anxiety, depression and desires, also lessened significantly. The current study suggests a possibility that alternative food treatment or alternative therapeutic drugs may assist heroin addicted patients to overcome acute and protracted withdrawal syndrome.

**Keywords:** heroin, functional food, acute withdrawal syndrome, protracted withdrawal syndrome