

Cystic Fibrosis Research News

Title:

Comparison of two pancreatic enzyme products for exocrine insufficiency in patients with cystic fibrosis

Authors:

C.J. Taylor ^a, R. Thieroff-Ekerdt ^b, S. Shiff ^c, L. Magnus ^c, R. Fleming ^b, C. Gommoll ^c

Affiliations:

^a University of Sheffield, Sheffield, UK

^b Former employee of Forest Research Institute, Inc., an affiliate of Actavis, Inc., Jersey City, NJ, USA

^c Forest Research Institute, Inc., an affiliate of Actavis, Inc., Jersey City, NJ, USA

What was your research question?

We wanted to compare the effectiveness and safety of two pancreatic enzyme replacement products, Kreon and Zenpep.

Why is this important?

In addition to respiratory symptoms, most people with cystic fibrosis (CF) lack the digestive enzymes produced by the pancreas, a condition called exocrine pancreatic insufficiency (EPI). Supplemental pancreatic enzyme products containing lipase are used to help digest food and relieve symptoms of poor digestion. Previous research indicates that the important ingredient in these pancreatic enzyme products, lipase, becomes less effective when exposed to moisture. Most pancreatic enzyme products overload each dose with extra lipase to overcome this loss of effectiveness over time; however, Zenpep is manufactured in a way that protects the lipase from moisture and does not contain extra lipase.

What did you do?

We compared Zenpep with Kreon in 96 patients with CF associated EPI aged 12 years and older who were already taking pancreatic enzyme replacement products. The patients were divided into 2 groups. Each group received either Zenpep or Kreon for 28 days and then switched to the other medication for another 28 days. The amount of fat in the stools, which indicates how much fat is being digested in the intestine, was measured. Patients also



Cystic Fibrosis Research News

kept daily diaries of their digestive symptoms such as bloating, abdominal pain, and intestinal gas.

What did you find?

There was no significant difference between the two medicines and the patients' fat absorption. Zenpep was equally as effective for improving fat absorption and relieving symptoms of poor digestion as Kreon. Side effects were mild and similar with both medicines; abdominal pain, diarrhoea, and intestinal gas were the most common side effects reported. No serious side effects were reported.

What does this mean and reasons for caution?

This means that pancreatic enzyme replacement therapy is possible without adding extra lipase. Zenpep may enable more accurate enzyme dosing in the treatment of patients with EPI due to CF or other conditions and thereby provide more predictable therapeutic effects.

What's next?

Zenpep has been approved in the US since 2009 and is being reviewed for use in the EU as Enzepi. If approved, Enzepi will be a newer treatment option for patients with EPI due to CF or other conditions.

Original manuscript in citation in PubMed

<http://www.ncbi.nlm.nih.gov/pubmed/27013382>