Test for Intestinal Permeability

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SUMMARY

Researchers from the Department of General Surgery at UCLA have developed an easy-to-use method to determine intestinal permeability that utilizes an FDA-approved non-absorbable dye.

BACKGROUND

The loss of intestinal barrier integrity plays a key role in the development and perpetuation of a variety of disease states, including inflammatory bowel disease, celiac disease, and sepsis. Furthermore, intestinal barrier loss plays a major role in the onset of sepsis and multiple organ failure during situations of intestinal hypoperfusion, such as trauma and major surgery. Therefore, the ability to detect intestinal barrier integrity and function loss may be useful for the early detection and/or prevention of disease recurrence or complications.

A variety of tests have been developed to assess intestinal epithelial cell damage, intestinal tight junction status, and consequences of intestinal barrier integrity loss. For example, one method assesses epithelial barrier integrity by measuring fatty acid binding proteins, glutathione S-transferase, or claudin-3 in a patient's blood or urine. Alternatively, another method measures levels of various sugars or polyethylene glycols in patient fluids. Unfortunately, these methods suffer from a lack of sensitivity and/or have high costs. Thus, an easy-to-use, sensitive, low-cost method to measure intestinal permeability would be greatly beneficial in clinical settings.

INNOVATION

Researchers from the Department of General Surgery at UCLA have developed a novel, easy-to-use method to determine intestinal permeability. The method utilizes an FDA-approved non-absorbable dye that patients drink and mass spectrometry analysis of patient blood at multiple time points following consumption of the dye. The method is sensitive enough to measure amounts as small as 1 femtomole (10-15). The inventors have estimated that a healthy subject that drinks the dye solution would have greater than 500 femtomoles per 5 milliliters of blood, which makes this assay highly sensitive. Importantly, even at the highest dye concentration used in the upcoming clinical trial, the solution would be 24-fold lower than the level considered safe by the FDA.

APPLICATIONS

Determine the intestinal permeability of patients at risk for sepsis, organ failure, or other conditions where loss of function of the intestinal barrier could lead to adverse symptoms or secondary effects.

ADVANTAGES

- FDA-approved
- High sensitivity
- Low cost
- Easy-to-use

STATE OF DEVELOPMENT

The inventors have completed the first phase of their clinical trial, which tested the method on 14 (8 normal, 6 critically ill) subjects and have demonstrated that the method can discriminate between the two groups. They plan to perform a larger clinical trial on patients with sepsis and to correlate clinical outcomes with the amount of dye absorption (up to 100 patients).

PATENT STATUS

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OTHER INFORMATION

KEYWORDS

Intestinal permeability, intestinal barrier loss, dye, sepsis, organ failure, inflammatory bowel disease, celiac disease, graft-versus-host, typhlitis

CATEGORIZED AS

- **Medical**
  - Diagnostics
  - Disease: Autoimmune and Inflammation
  - Disease: Digestive System
  - Disease: Infectious Diseases

RELATED CASES

2017-771-0

Country	Type	Number	Dated	Case
United States Of America	Issued Patent	12,044,683	07/23/2024	2017-771

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