

Das-1 Monoclonal Antibody for Screening and Diagnosis of Precancerous Conditions of the Stomach

Background

Gastric cancer is the seventh leading cause of cancer deaths in the United States and is a major cause of death worldwide, especially in developing countries. Annually, about 24,000 Americans will be diagnosed with gastric cancer. Worldwide, there are approximately 700,000 new cases of gastric cancer. Chronic gastritis, intestinal metaplasia, pernicious anemia, gastric polyps or *Helicobacter pylori* infection of the stomach are all considered to be risk factors for the development of gastric cancer.

Approximately 35-50% of US population infected with *H.pylori* and 40-50% of infected subjects develop the precancerous condition known as intestinal metaplasia in the stomach. Gastric intestinal metaplasia (GIM) is a change in the lining of the stomach whereby the lining of the stomach is replaced by cells resembling the lining of the intestine. Previous studies concerning whether GIM of the small intestinal or colonic phenotype predisposes gastric cancer have not yielded unequivocal results.

Thus, there is significant unmet medical need to screen at-risk patient populations for gastric cancer.

Description of the Technology

A monoclonal antibody, named Das-1 that reacts specifically to a colonic epithelium protein called the colon epithelial specific protein (CEP) was developed for screening and diagnosing patients with the precancerous GIM condition. This monoclonal antibody reacts with CEP of colon and Barrett's epithelium of the esophagus, which is a columnar metaplastic change, but does not react with normal small intestinal, gastric, esophageal and gastric-esophageal junctional epithelium. Das-1 antibody is also negative to esophagitis and squamous cell carcinoma.

Das-1 monoclonal antibody was tested in two groups of tissue samples. When tested in patients without gastric cancer but with GIM, the antibody reacts strongly with GIM. Furthermore, a large percentage of gastric cancer patients positive for GIM showed stronger reactivity with the monoclonal. This revealed that the presence of colonic phenotype of GIM is strongly associated with gastric carcinoma and that Das-1 antibody can be used to screen and identify patients prone to develop gastric cancer. Patients identified as more prone to develop gastric cancer could be followed closely by endoscopic examinations. Subjecting only those patients who are at risk of developing gastric cancer would decrease the cost to healthcare significantly.

Advantages

- Commonly used diagnostic methods such as endoscopy, X-rays of upper gastrointestinal tract and fecal occult blood test have limitations and are very expensive to perform.
 - Accuracy of endoscopic diagnosis is poor and intestinal metaplasia can be recognized only after extensive endoscopy.
 - sampling errors are common and intestinal metaplasia can be recognized with only powerful endoscopes.

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- Unlike breast cancer, cervical and colorectal cancer, gastric cancer does not have an accepted screening procedure

Applications

- For screening and diagnosing at risk patients for gastric cancer.
- For research applications.

Patent Status

- United States and PCT patent applications filed. The US patent application was published (Publication No.:US2003-0077675) on 04/24/2003.

Licensing Opportunity

- This technology is available for non-exclusive or exclusive license.

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File RWJ 00-01/Das