WavSTAT4 Optical Biopsy System® for colorectal cancer diagnosis

TECHNOLOGY

WavSTAT4 Optical Biopsy System® has been developed by SpectraScience for the real time diagnosis of pre-cancerous colon polyps (≤5mm). WavSTAT4® uses laser-induced autofluorescence to obtain an objective, in vivo analysis of polyps during colonoscopy.

A low-intensity and non-damaging laser light is directed from the WavSTAT4® mobile console through an optical fibre mounted in the single use WavSTAT4® optical biopsy forceps. These are directed through the working channel of the colonoscope (a standard endoscope) and brought into direct contact with the polyp. The polyp tissue absorbs the laser light, resulting in the excitation of the tissue being examined. The resulting autofluorescent signal is sent back and analysed by a waveform analysis algorithm in the console, to diagnose precancerous colon polyps. A green ‘non-suspect’ or a red ‘suspect’ result is displayed on the console’s screen within seconds. A biopsy sample can be taken using the forceps.

WavSTAT4® is CE marked and is currently in use at St James University Hospital in Leeds, as part of a European trial. A full commercial launch in the UK is expected in Q2 2015. WavSTAT® has been developed through the National Institute for Health Research (NIHR) Colorectal Therapies Healthcare Technology Co-operative (HTC). The HTC engages industry, NHS, scientists, charities, engineers, patients and public in identifying areas within colorectal therapies where development of new technology would be of benefit to patients.

POTENTIAL FOR IMPACT

Colorectal cancer (CRC) is the third most common cancer in the UK. The majority of CRCs...
develop from benign adenomatous polyps in the bowel wall. A series of genetic alterations usually results in the transformation of normal epithelium to an adenoma, which in some instances mutates into a carcinoma. The disease progresses slowly and takes approximately 10 years for an adenoma to develop into cancer. This long latency period provides an opportunity for early detection of the disease.

Colonoscopy is the endoscopic examination of the large bowel and the distal part of the small bowel with a fibre optic camera on a flexible tube passed through the anus. It can provide a visual diagnosis and provides the opportunity for removal of suspected polyps. Once polyps are removed, they can be studied with the aid of a microscope to determine if they are precancerous or not. Removal of these adenomatous polyps reduces the risk of future CRC. Macroscopic differentiation between a hyperplastic (has virtually no chance of becoming cancerous) and an adenomatous polyp during colonoscopy is difficult.

According to the company, WavSTAT4® has the potential to distinguish between hyperplastic and adenomatous polyps during colonoscopy. The company claim that WavSTAT4® may reduce the risks associated with polyp removal during the colonoscopy (e.g. bleeding and perforation). If WavSTAT4® proves to be effective, it has the potential to reduce the number of histological biopsies and costs involved in processing current biopsies.

This technology is predicted to have an impact on the following domain of the NHS Outcomes Framework (see: www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk): Domain 1 Preventing people from dying prematurely.

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**


**ONGOING STUDIES**

COMPANY INFORMATION

According to the company, future generations of WavSTAT4® will incorporate scattering spectroscopy diagnostic technology, together with laser-induced fluorescence, to address the diagnosis of precancerous lesions or other cancers in the colon and to improve the overall diagnostic capability.

INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.