PRESS RELEASE

Results from study conducted at SDG Clinical Research showing effectiveness of blood-based colorectal cancer screening test published in The New England Journal of Medicine

- ECLIPSE study results support use of blood-based test to help close the colorectal cancer screening gap in the United States

San Deigo , CA March 14, 2024 – Results of a study showing the effectiveness of a blood test in detecting colorectal cancer (CRC) in adults at average risk for the disease were recently published in The New England Journal of Medicine, one of the world's leading medical journals. The ECLIPSE study evaluated the performance of Shield™, a blood-based screening test developed by Guardant Health, and was conducted at **SDG Clinical Research** along with more than 200 other study sites across 34 states.

The Shield test works by detecting CRC signals in the bloodstream from DNA that is shed by tumors, called circulating tumor DNA (ctDNA). In the study, the ability of the Shield test to identify individuals with CRC was on par with the ability of guideline-recommended non-invasive screening tests.

Shield "An accurate blood-based screening test that people are willing to complete has the potential to be an important tool to increase overall colorectal cancer screening rates, particularly among underserved communities," said **Andrew Cummins, MD SDG Clinical Research** and one of the investigators of the ECLIPSE trial. "We are proud to have participated in the ECLIPSE study, which reinforces the potential for a blood test to provide an effective new option for people who might not otherwise complete recommended screening."

ECLIPSE study results

One of the largest studies of its kind, ECLIPSE evaluated the performance of the Shield test in detecting CRC in average-risk adults 45 to 84 years old, compared to a screening colonoscopy. More than 20,000 people participated in the study. The results published in The New England Journal of Medicine, available The New England Journal of Medicine: Research & Review Articles on Disease & Clinical Practice (nejm.org), showed that Shield demonstrated 83% sensitivity in detecting people with CRC, a result on par with guideline-recommended non-invasive CRC screening methods in which overall sensitivity ranges from 74% to 92%, with 90% specificity.[1] The Shield test had 88% sensitivity in detecting pathology-confirmed CRC Stages I-III.

About Colorectal Cancer

CRC is a major public health problem globally and is the second leading cause of cancer-related deaths in the United States.[2] An estimated one out of three eligible Americans are not currently getting screened for CRC as recommended,[2] which is well below the Centers for Disease Control and Prevention's goal of 80% of all eligible individuals.[3] This significant gap in CRC screening rates highlights the urgent need for an accurate screening test that is easy and convenient for people to complete. A blood-based screening test like Shield has the potential to help overcome barriers associated with other CRC screening modalities and dramatically improve overall screening rates.

About the ECLIPSE study

The prospective ECLIPSE study evaluated the performance of the Shield test in detecting signs of CRC compared to a screening colonoscopy in adults ages 45 to 84 at average risk for CRC from across the U.S.

The study included more than 200 clinical trial sites in rural and urban communities across 34 states. Study data includes 12% Black, 13% Hispanic and 7% Asian American populations. Enrollment among Black Americans was above average for a clinical trial, which is important given the disproportionate impact of CRC on the Black community.[4]

About Shield

The Shield test detects colorectal cancer signals in the bloodstream from DNA that is shed by tumors, called circulating tumor DNA (ctDNA). Specifically, the test identifies certain characteristics of the DNA that may indicate the presence of cancer. Following a routine blood draw that requires no advance preparation, the test result is available approximately two weeks after the sample is received. Shield is intended to be complementary to, and not a replacement for, current recommended CRC screening methods. The test result will be either positive or negative. A negative result does not rule out the presence of cancer. Patients with a positive result should be referred for a diagnostic colonoscopic evaluation. More information about the Shield test is available at bloodbasedscreening.com.

About: SDG Clinical Research

www.sandiegogastro.com

References

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