
FoodMarble aces pivotal clinical trial with Johns Hopkins

Major healthcare authority Johns Hopkins has awarded Irish company FoodMarble's portable hydrogen breath tester with a 'Gold Standard.'

An ingenious medtech device created by Dublin start-up FoodMarble has completed its first clinical trial with the influential [Johns Hopkins University](#), one of the world's leading centres in gastroenterology.

The trial at Johns Hopkins Medicine, led by Prof Jay Pasricha MD has found FoodMarble's AIRE portable hydrogen breath tester, to exceed the current 'Gold Standard' clinical test for the diagnosis of Small Intestinal Bacterial Overgrowth (SIBO).

Dublin-based FoodMarble is bringing its digestive solution to patients in the US and Canada and is targeting €4m in sales by the end of 2021.

Last year FoodMarble raised €1.2m in a funding round led by a Halo Business Angel Network (HBAN) investor syndicate along Enterprise Ireland, SOSV and Delta Partners.

The company was founded by CEO Aonghus Shortt along with co-founders Lisa Ruttledge and Peter Harte.

A breath of fresh AIRE

SIBO is a very common disorder where there are excessive bacteria present in the small intestine. The true prevalence of SIBO in the general population is largely unknown, with some studies estimating its occurrence in up to 15pc of healthy individuals. It is also largely associated with many other common clinical conditions, including irritable bowel syndrome, where 40-80pc of IBS patients have SIBO.

The FoodMarble AIRE is the world's first personal digestive tracker. FoodMarble AIRE, is a commercially available, personal hydrogen breath test device which connects via Bluetooth to a smartphone app, providing immediate results and helps users optimise their diet using long-standing clinical technology but in a handheld, personal device

The AIRE device was also deemed to enable real-time meal related breath testing and symptom logging in what could be a huge step forward in gaining greater understanding of these difficult to treat issues.

“The Covid pandemic has emphasised the need to adopt innovative tools to maintain important patient testing,” said Robert Ganz, clinical advisor to FoodMarble.

“AIRE enables the patient to test in the safety and comfort of their own home. AIRE also gives the patient the power to check their response to the antibiotic treatment by repeat testing. Furthermore, SIBO relapse is also very common and can occur within months of the initial clearance of infection. Therefore monitoring with AIRE can us help identify the early the signs of relapse before the infection reoccurs .”

Gold standard

The trial compared FoodMarble’s ‘AIRE’ device to the current gold standard Lactulose hydrogen breath testing (LHBT) for the diagnosis of SIBO.

30 patients suspected of SIBO and 14 healthy subjects, recorded baseline and post-prandial hydrogen breath and symptoms (bloating, abdominal pain) in response to their morning and evening meals using the AIRE device and app. A LHBT was also performed using AIRE and compared against a commercially available mail-in, LHBT kit using concordance analysis.

superior. The AIRE test was positive in every instance that the mail-in LHBT test was positive, however, AIRE also picked up two additional positive cases which the mail-in LHBT kit did not.

“We have witnessed a clamour for greater access to SIBO testing from those who suspect that they may be affected,” said FoodMarble co-founder and CEO Aonghus Shortt.

“This has translated into growing interest from gastroenterologists, especially during a time when they often cannot see their patients in-person and must rely on telehealth and remote monitoring. We strongly believe that tracking the response to multiple meals over several days, instead of a single-snapshot test, can better reflect typical digestive processes and support better diagnosis.

“To see our technology clinical validated is extremely satisfying. We will continue to develop and help validate new tools for clinicians, which will ultimately help patients overcome debilitating and harmful conditions.”