

Microwave health tech innovator launches \$2m clinical trial

A Scottish health-tech innovator is undertaking a rigorous clinical trial which could transform the fortunes of its microwave treatments in the US.

Emblation's Swift® device is already being used by more than 1,000 clinicians across the States, but the new trials should help achieve new, extended clearance from the US Government's Food and Drug Administration (FDA).

A trio of renowned dermatologists will recruit a total of 110 patients across research centres in three US cities and each subject will receive treatment once a month for up to four months if needed, with progress and results blindly reviewed by expert assessors.

Crucially, [the \\$2m dollar study is a type known as pivotal trial](#), meaning that Swift®'s treatment for warts and verrucae will go head-to-head with cryotherapy, one of the most widely-used treatments for persistent skin lesions, comparing how effective and safe both treatments are.

Dr Matt Kidd, Director of Research and Development with the Stirling-based firm, said: "No healthcare system in the world is as commercially important than that in America, which is why it is so heavily regulated.

“This clinical trial is the culmination of years of research and development of our products to target this market. Once the findings are complete, it should transform the way we can market Swift® treatments.”

Microwave treatment offers unique advantages because it is accurate, repeatable and does not affect surrounding tissues. However, Swift®’s current clearance in the US is as a “general indication of use” in dermatology – and it cannot be marketed as a specific treatment for warts and verrucae.

Dr Kidd added: “This is a major milestone for us and it has been a long process to get to this stage, ultimately made possible by the fact that Emblation attracted significant investment.

“It is now our very clear hope that the results will allow us to change how our device is labelled, while also demonstrating that Swift® treatments offer clear advantages over cryotherapy.”

Recruitment of patients to take part [in the research](#) is now being led by three renowned dermatologists in Chicago, Miami and Nashville. The randomised element of the trial will be in whether patients are assigned Swift® microwave treatment or cryotherapy, which involves freezing a wart or verrucae.

All three dermatologists involved in the clinical research are globally renowned. Dr Ashish Bhatia in Chicago is recognised for his surgical work, including reconstructive surgery and scar revision.

Dr Jill Waibel in Miami is a world expert in dermatologic laser surgery, while Dr Michael Gold in Nashville is also a sought-after international expert on the use of lasers and energy-based devices in dermatology.

When all 110 patients have passed the three-month study mark after treatment, results will be collated and independently

assessed and an initial report will be drafted on the efficacy and safety of the treatments. That will be submitted to the FDA, which oversees the safety of all drugs and medical devices in the US.

Once all patients have passed the full 12-months of the study, a final report will be created, giving a definitive picture of Swift®'s effectiveness in treating warts and verrucae and in preventing reoccurrence – as compared with cryotherapy.

The clinical trial team at Emblation hope the final findings will be published in mid to late 2024, marking another major milestone for the firm, which was founded by two scientists who met while studying at Heriot Watt University in Edinburgh.

Swift® was launched to the podiatry market in 2016 and quickly made an impression with clinicians. The firm's growth was boosted in 2021, when it was backed by London-based specialist healthcare investors at Apposite Capital.

As well as making possible the new clinical trial, that cash injection has also fuelled Emblation's rapid growth across Europe, the US and the Middle East. In December 2022 the firm announced the acquisition of a specialist US distributor in a seven-figure deal.

It was also revealed that more than 400 Swift® devices had been rolled out across the US, with more than 1000 practitioners trained in its use and more than 50,000 treatments carried out on skin lesions. Globally, Swift® has been used in more than 300,000 treatments.

The firm was founded by Gary Beale and Eamon McErlean, who met during post-graduate studies at Heriot Watt university. The pair went on to launch Swift® in 2016, as a radical new treatment in the podiatry & dermatology sectors.

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