



First subject dosed in psilocybin trial for rare headache disorder



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The first patient has received a low dose of Beckley Psytech's psychedelic medicine psilocybin in a clinical trial for short-lasting unilateral neuralgiform headache attacks (SUNHA), a rare disorder.

The UK company says that SUNHA is a debilitating condition that is estimated to affect 40,000 patients in US and Europe. It is characterised by short, extremely painful headaches that can occur many times a day, and

there is currently no approved treatment for the condition.

The [phase 1b trial](#) should generate results in early 2022 and is something of a departure for the use of psychedelic medicines, which are typically being tested at higher doses in carefully controlled environments and alongside psychological therapy for indications like depression and post-traumatic stress disorder (PTSD).

In April, for example, researchers at Imperial College London's Centre for Psychedelic Research [reported](#) that a psilocybin formulation developed by Compass Pathways was more likely to help patients achieve remission from depression than a widely-used antidepressant medicine.

In this latest study, psilocybin – the active ingredient in magic mushrooms – is being administered as a straight pharmacological intervention, at a range of doses that are expected to be too low to cause hallucinogenic effects.

It will enrol up to 12 patients to try to show proof of concept and – if successful – the recommended dose to take forward for further development. Patients will receive doses on days one, six, and 11, with a follow-up visit on day 25.

It will explore the change in frequency, duration, and intensity of headache attacks with psilocybin treatment, as well as the drug's effects on cognition in people with chronic SUNHA, as well as safety and tolerability.

At the moment, SUNHA is generally treated off-label using epilepsy medicines like lamotrigine, topiramate and gabapentin, but there is limited data backing their efficacy.

“The potential medical advantages of psychedelic agents, such as psilocybin, could be transformational to the quality of life for those affected by this disease,” said Cosmo Feilding Mellen, chief executive of Beckley Psytech.

The UK company recently [raised](#) an impressive £58 million (around \$80 million) in an oversubscribed second-round financing that will help fund the development of its psychedelic therapies.

Along with psilocybin, the company is also working on an intranasal formulation of 5-MeO-DMT, a psychedelic compound found in plants and at least one species of toad, as a treatment for treatment-resistant depression (TRD).

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