SarcoidosisUK-funded Clinical Trial for the Treatment of Pulmonary Sarcoidosis with Antibiotic Azithromycin Shows Promising First Results.

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In 2018, SarcoidosisUK funded a major research project at the University of Hull into the use of the antibiotic azithromycin to treat pulmonary sarcoidosis, a disease which is fatal for some. The clinical trial first results show a significant reduction in cough count and meaningful improvements in sarcoidosis-related quality of life after three months of azithromycin treatment. The £60,000 trial was carried out in 2019/20 and funded by generous donations to Charity SarcoidosisUK's 20th Anniversary Campaign.

Sarcoidosis is characterised by the formation of inflammatory cells (called granulomas) in affected organs. Each patient's sarcoidosis is unique; while some sarcoidosis patients are able to live reasonably normal lives, many others endure chronic pain, organ damage and a very poor quality of life. Sarcoidosis is fatal in around 5% of cases, usually when the heart or brain is affected.

Every year in the UK about 3,000 to 4,000 people are diagnosed with sarcoidosis and there is currently no known cure for the condition. Treatment options are also limited and rely on supressing the immune system. However, these treatments often have adverse side effects or are ineffective. New treatment options are therefore urgently required.

In 2017, exciting new research conducted in mice at the University of Vienna suggested that sarcoidosis granulomas are formed by the activation of a protein called 'mTOR'. The 2019/20 University of Hull clinical trial was led by Respiratory Consultant and ILD Research Specialist Dr Simon Hart, who identified that the antibiotic Azithromycin is known to reduce mTOR activity in inflammatory cells and is safe to use with sarcoidosis patients.

Chronic cough is a common and distressing symptom for many people with pulmonary sarcoidosis. Dr Hart and his research partners at the University of Hull and Hull University Teaching Hospitals NHS Trust set out to assess the potential efficacy of azithromycin in patients with sarcoidosis and self-reported cough.

Dr Hart and his team conducted a non-controlled, open-label clinical trial of azithromycin involving 21 pulmonary sarcoidosis patients from the Hull Sarcoidosis Clinic who reported a chronic cough. The participants took 250 mg of the drug once daily for 3 months.

The first results from the clinical trial have now been published in European Respiratory Journal Open Research. The results show that after 3 months of treatment with azithromycin, there were improvements in a range of cough metrics and all patient-reported outcomes. More than half of the patients reported clinically meaningful improvements in cough-related quality of life, and more than three quarters had clinically meaningful improvements in sarcoidosis-related quality of life. The median reduction in cough count was 49.6% and the drug was well tolerated by the patients.

The clinical trial results are promising and support further trials. Dr Hart and his team conclude that azithromycin should be tested as a treatment for sarcoidosis cough in a randomised placebo-controlled trial.

Henry Shelford, SarcoidosisUK Chairperson expressed the importance of the trial's results:

"This is a really exciting, potentially ground-breaking piece of research. The initial results show that azithromycin produces a significant improvement for people with pulmonary sarcoidosis and the consequences of this are far-reaching. Using this existing drug, that is relatively cheap and approved for use in the UK, offers the potential for a fast route to a new treatment. The fact of the reaction may also offer highly important insight into the disease mechanism, which itself might offer new treatment options. We thank everyone who has donated or supported the charity - without you this research wouldn't have been possible. We wholeheartedly support the conclusion of Dr Hart and his team in relation to further trials for this promising treatment."

Dr Hart said: *"Chronic cough is a distressing symptom for many people with pulmonary sarcoidosis, and for some it can have a big impact on quality of life. An appealing strategy for investigating new treatments for sarcoidosis is to 're-purpose' existing drugs that are safe for long-term use. In our non-controlled,*

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open-label trial in people with sarcoidosis who reported a chronic cough, 3 months of treatment with azithromycin led to improvements in a range of cough measurements, without significant side effects. The study did not have a placebo (dummy) arm so we cannot say how much of the effect was due to a placebo response, but we believe that the improvements were sufficiently large to merit further investigation of azithromycin as a treatment for sarcoidosis cough."

About SarcoidosisUK

SarcoidosisUK is the UK's national sarcoidosis charity, providing information and support to anyone affected by sarcoidosis. They also raise awareness and fund research into a cure for the condition. They are committed to funding at least one major research project each year until a cure has been found and they are one of the largest sarcoidosis research-funders in the world.

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Trial Results

https://openres.ersjournals.com/content/6/4/00534-2020

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