Premature termination of a Clinical Trial

Full title of the clinical Trial:

Systems medicine analysis of sarcoidosis by targeting mTOR in a

pilot study of sirolimus as treatment in patients with sarcoidosis

Eine Pilotstudie zur Untersuchung der Wirksamkeit und Sicherheit von Sirolimus als Therapie der Sarkoidose

EudraCT Number: 2017-004930-27

Sponsor: Medical University of Vienna
Represented by (name): Stary Georg, Assoc.Prof.Priv.Doz.Dr.

Reason for premature termination of the clinical trial:

Termination of patient inclusion

Study results (if available):

While topical treatment did not alter cutaneous lesions, systemic treatment resulted in clinical and histologic remission of skin lesions in 7 of 10 patients. We identify papular, nodular, plaques, scar and tattoo associated cutaneous sarcoidosis as responding morphologies presenting a long-lasting effect beyond the period of our study. There were no serious adverse events. The most common side effects were mild in nature and included skin reactions (62,5%) and gastrointestinal symptoms (43,75%). All resolved when the treatment was completed. We identify beneficial effects on other affected organs, including lungs, eyes and spleen. Treatment with mTOR inhibition resulted in delayed significant increase in quality of life measured with King´s sarcoidosis questionnaire. We

observed important alterations in skin immune and structural cell composition during systemic treatment. Peripheral blood immune cells present a delayed shift, more precisely a rise in T cells and non-classical monocytes at the end of the study.

Date and Signature of Sponsor representative:

Vienna, Oct 15, 2022