Study title: The Role of Uric Acid Metabolism in Pathogenesis of Anaphylaxis: the Effect ofAllopurinol on Experimentally-induced Allergic Reactions to Peanut in Peanut-Allergic Adults; a randomised, double-blind placebo-controlled, cross-over, single-centre study (RUPA)

EudraCT Number: 2017-005060-18

MHRA CTA acceptance number: CTA 48980/0009/001-0002

The trial was terminated early as a result of the COVID-19 pandemic and the primary outcome analysis has not been completed as the study was underpowered for the primary outcome and the results will not be published.

In the power calculation we calculated that 20 participants would give 80% power to detect a 10% (placebo) vs 50% (allopurinol) effect size difference at 5% significance level. The target completion number for the study was therefore 20 patients.

In total 24 patients were consented of whom only 6 patients completed the study before it was terminated early because of COVID-19 pandemic. At the outbreak of the pandemic there were 6 patients actively in the trial, but it was not possible for them to complete the study. This is because the oral food challenges required prolonged spells in hospital (>8 hours per day) with close contact between staff and patients, which for infection prevention and control reasons was not possible. The remaining 12 were withdrawn before the COVID-19 pandemic - 6 did not meet the criteria after screening visit 1 or withdrew due to schedule clashes and 6 did not meet the criteria after the 3rd screening visit.

Recognising that it would not be possible to restart the study until covid was no longer a threat, after discussion with the funder, the difficult decision was taken to terminate the study in spring 2021. None of the patients were receiving the IMP (allopurinol) at time of termination. As the IMP is already licenced in the UK for the treatment of gout, there were no consequences for the overall risk benefit assessment of the IMP. As only 6 participants completed the study, it was underpowered for the primary outcome, this analysis cannot be completed and the results will not be published in a peer reviewed journal.