Protocol of a Randomised, Single Blind, Placebo-controlled RESCAP Intervention Study to Determine the Safety of RESCAP in Diabetes: RAPID Protocol – Rationale and Design

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Citation: *European Cardiology Review* 2020;15:e41. **DOI:** https://doi.org/10.15420/ecr.2020.15.1.PO18

Type 2 diabetes (T2D) affects 5.3% of the world's population and has a huge impact on healthcare costs, morbidity and mortality. Low-grade chronic systemic inflammation results in complications, such as retinopathy, end-stage renal disease, diabetic wounds and pregnancy complications. Alkaline phosphatase (AP) supplementation restores insulin and blood-lipid chemistry in preclinical models. A human field study in T2D patients reported that AP in faeces is reduced 50%.

We propose oral AP supplementation in T2D patients.

AMRIF, leveraging its RESCuing Alkaline Phosphatase (RESCAP) platform, is developing therapies for T2D and other chronic inflammatory diseases. The RESCAP in Diabetes (RAPID) study is an exploratory interventional, multicentre, blinded, randomised controlled trial designed to determine the safety of RESCAP in T2D patients with high HbA_{1c}, partially responsive to standard care treatment on metformin. The safety of bRESCAP has been extensively investigated. The safety and efficacy of bRESCAP has been established in a variety of preclinical disease models and in a clinical trials, either IV or SC formulations.

The Preventing Systemic Inflammation After Cardiac Surgery With Alkaline Phosphatase (APPIRED-III; NCT03050476) study of RESCAP is a Phase III study in cardiothoracic surgery patients. In topical/oral settings, safety and efficacy has been established in patients with IBD.

RAPID may yield long term safety data (primary outcome) and health benefits in T2D. Secondary outcome parameter changes: e.g. HbA_{1c}, blood lipid chemistry, low-grade systemic inflammation, adverse events and general well-being. Duration: 9 months (the clinical phase). Upon ethical approval, RAPID is conducted under ICH GCP. ■