Appetite supressing tablet using natural products

Key benefits

- Phase I clinical trial data demonstrating boost of potent satiety hormone and reduction in calorie intake
- Pre-clinical human gut tissue results and Phase 1 clinical trial data demonstrate efficacy of combination nutrient delivery to the colon.
- Treatment is well tolerated with no reported side effects.
- Nutrient combination and targeted colonic delivery under global IP protection
- Huge market to be addressed as obesity costs the NHS over £5Bn and another £300M in hours of social care. Costs in the US for obesity - related care in 2018 was $344Bn and affects nearly 40% adults.

Background

Weight gain and resulting obesity (defined as having a Body Mass Index of over 30) are implicated as risk factors for many diseases ranging from Type 2 Diabetes to cancer and dementia. Thus, it is critical to identify effective therapies to assist people in maintaining a healthy weight. This area of critical importance to a large proportion of the public, as in England alone, 64% of adults are overweight or obese (67.1% of men and 57.2% of women according to Health Survey England, 2017). Researchers at Queen Mary University of London have identified specific combination of nutrients capable of boosting release of the potent appetite reducing hormones, GLP-1 and PYY. We have successfully completed a Phase I trial in obese volunteers. Data from this study demonstrates the efficacy of this novel capsule formulation released in the colon reduces food intake and increases the release of potent appetite reducing hormone, PYY.

The Problem

- 1.9 Billion people worldwide are overweight of whom 650 million are obese (WHO, 2019)
- The four most common forms of cancer, i.e. bowel, kidney, ovarian and liver, have a greater association with obesity compared to any other lifestyle factor (Cancer Research UK, 2018).
- No preventative or effective interventional therapy
- Only effective treatment for significant weight loss and resolution of type II diabetes is bariatric surgery. Roux-en-Y gastric bypass, a type of bariatric surgery, induces 30-40% weight loss and is maintained for 10 years post-surgery (Mantziari *et al*, Obes Surg, 2020). However, this is an irreversible procedure and incurs a significant cost, is not widely available and only recommended for severely obese patients.

The invention

In pre-clinical studies performed on colonic human tissue, we identified a) a specific combination of nutrients that stimulate cells to release hormones that induce the feeling of satiety and reduce appetite and calorie intake, b) the colon as an important yet under-used site of appetite regulation. We have validated our claims by demonstrating that we can boost the release of appetite-reducing hormones from specialised gut cells in human tissue laboratory experiments and in the clinic. The patent has been filed broadly to protect in the following territories; China, India, Europe and the US.

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Link to inventor/PI website (Dr Madusha Peiris)
https://www.qmul.ac.uk/blizard/staff/centre-for-neuroscience-surgery-and-trauma/staff/madusha-peiris.html
https://www.bowelcancerresearch.org/decoy-bypass

Project Development and Results

To test the capacity of the response of gut enteroendocrine cells in situ, we completed a Phase I clinical trial in obese volunteers using a placebo controlled, randomised, double-blinded, crossover study. In our acute, first-in-human study, we found participants consumed *fewer* calories when treated with the active capsules compared to the placebo (Figure 1A,B). In addition, during the active treatment, circulating levels of appetite-reducing hormone PYY *increased*, compared to placebo (Figure 1C,D).

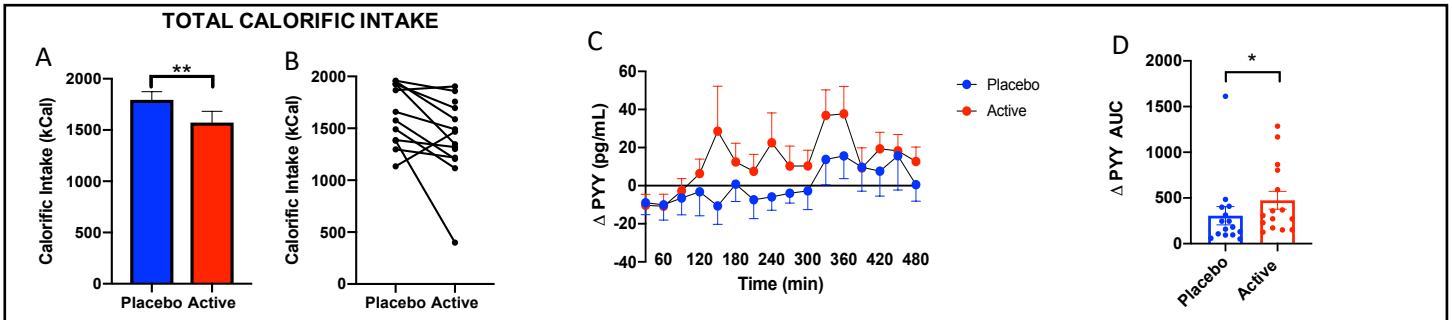

Figure 1: A,B: Calorific intake following placebo and active treatment after breakfast and lunch (both were standardised meals and identical for all volunteers in active and placebo). C: Circulating levels of PYY relative to baseline in active vs. placebo (mean ± standard error of the mean) D: Area under the curve data representing PYY relative to baseline in placebo vs. control (Paired Student t test, $p < 0.05$).

Competition

We are aware of non-surgical technologies such as that of Plenity (absorbent hydrogel capsules taken before eating that expands and fills the stomach) and Obalon (intragastric balloon inflated in stomach for 6 – 12 months) but they have limited efficacy with weight loss of a maximum 5% body weight. However, these treatments do not significantly impact on the release of anorectic hormones which are the long-term mediators of satiety and are critically reduced in overweight/obese individuals.

Although, invasive methods to limit Obesity such as gastric bypass, bariatric surgery can provide benefit to clinically morbid patients, majority of obese individuals would not have access to it. Furthermore, these invasive methods function long term by suppressing appetite because most of the stomach and lower gut is removed. However, it would be much safer to potentiate this endocrine response via a safer method such as the one that we propose. Additionally, this method would be accessible to those who are overweight and assist in weight loss prior to the development of obesity. Therefore, a much greater population would benefit from the proposed treatment.

The GLP1 receptor agonists being trialled by some companies such as liraglutide (Saxenda) are available as treatments for weight loss via a subcutaneous injection. While, this treatment has a slightly higher level of efficacy compared to other treatments such as Orlistat, there are serious adverse events including increased heart rate, increased risk of developing pancreatitis and induction of nausea (Mehta *et al*, Obes Sci Pract, 2017).

Commercial development

This opportunity offers huge potential to safely address a global problem that the increase in obesity across the globe costs the NHS £6BN a year in the UK alone each year.

We are already moving into a Phase II clinical trial for which we have support. However, we are seeking a licensing partner to drive the development into Phase II and to the market. We are also exploring the feasibility of improved methods of formulation so that we can offer a single pill at a concentrated dose to be taken before meals.

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