



# Is this the end of obesity?

First time in human trials begin at the McMichael Centre for new drug - PP1420

*Ben Wilkins*

Researchers at the McMichael centre may render personal trainers redundant with a new drug for appetite regulation. PP1420 mimics pancreatic polypeptide (PP), a hormone produced naturally in our pancreas after every meal, making us feel full. After pre-clinical testing on rats, the team, led by Dr Trisha Tan, under Principal Investigator Professor Steve Bloom, is giving the drug to humans for the first time.

Currently in Phase 1, eight carefully selected healthy volunteers, male 18-50, are treated with PP1420, in 3 increasing doses, one dose every 6 weeks, and 4 are given a placebo. The team monitor vital signs, food intake,

body-weight, pharmacokinetic plasma profiles (levels the drug gets to in the body) using state-of-the-art mass spectrometry to determine the relationship between dose and tolerability.

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Carrying out the Phase 1 first-in-man trial academically as oppose to commercially, Prof Bloom is hoping to demonstrate that ‘hospitals can develop drugs and make them a success’.

When asked if they felt they could be

putting personal trainers out of work, Dr Tan insists it will never supersede exercise but perhaps it will give obese people the incentive to lose more weight by exercise

The team would like to thank the senior nurses and staff at the Sir John McMichael Centre for their expertise, for ‘giving us many things to think about and keeping us on the straight and narrow’ says co-investor Dr Field.

The study is funded by the Wellcome Trust, who are currently looking for companies to sponsor phases 2 and 3. For more information, contact Dr Trisha Tan at [t.tan@imperial.ac.uk](mailto:t.tan@imperial.ac.uk) or contact the Sir John McMichael Centre on 020 8383 8082.

## The Route to Drug Development

### Preclinical

Studies in rodents (and other animal species) looking for evidence of effect as well as an upper limit of safety – the No Observed Adverse Effect Level (NOAEL).

### Phase 1 – First time in human

The primary aim is to explore safety and tolerability in humans; doses are gradually increased and vital signs monitored.

### Phase 2 – Proof of efficacy

Small group of patients with specific doses to identify a series of doses that works.

### Phase 3 – Definitive study

Using a larger group of subjects, phase 3 is a demonstration that the drug works - in this case showing a significant and meaningful reduction in weight in the target population. (Licensing requires 2 x phase 3 studies, and drugs can only be licensed for use in the doses used in the study).

### Phase 4

Studies conducted when the drug is licensed.