Title

Acute glycemic and insulin response of Fossence™ alone, or when substituted or added to a carbohydrate challenge: A three-phase, acute, randomized, cross-over, double blind clinical trial

Participants

Inclusion criteria

- 18 – 65 years of age.
- BMI of 18.5 - 30 kg/m^2 (both inclusive).
- Blood pressure < 140/90 mmHg.
- No major illness or surgery requiring hospitalization within 3 months of the first study visit after screening.
- No history of cardiovascular, metabolic, respiratory, renal, gastrointestinal or hepatic disease.
- Subject may be a male or a non-pregnant, non-lactating female, at least 6 weeks postpartum prior to screening visit.
- Willing to maintain habitual diet, physical activity pattern, and body weight throughout the study.

Exclusion criteria

- Failure to meet all the inclusion criteria.
- Previous bariatric procedure.
- No chronic disease such as type-1 or type-2 diabetes mellitus
- Fasting plasma glucose >100 mg/dL (or >5.6 mmol/L) as assessed at the first visit.
- No gastro-intestinal disorder such as Crohn's disease, coeliac disease, irritable bowel syndrome.
- Use of medications known to affect glucose tolerance; however stable doses of oral contraceptives, acetylsalicylic acid, thyroxin, vitamins and mineral supplements or drugs to treat hypertension, hyperlipidemia, anxiety/depression or osteoporosis are acceptable.
- Any known food allergies or intolerances.
- No strong dislike of or intolerance to sweetened beverages or inulin.
- Smokers.
- Alcohol consumption of no more than 10 drinks per week for women and 15 drinks per week for men. One drink is defined as either 5oz wine, 341ml of beer/cider or 1.5 oz distilled alcohol.
- History of cancer in the prior two years, except for non-melanoma skin cancer.
- Participants who do not understand English.
- Presence of any condition, illness or drug use, which in the opinion of the study physician increases the risk to the subject or to others or may affect the results.

Consent and screening procedures

Individuals willing to be considered for participation were invited to come to the research centre to have the study procedures explained to them and be given a copy of the consent form which they could either sign then, take away to sign at a later date, or decline to participate. Participants were

encouraged to ask any questions they may have had and not to sign the consent form until all of their questions had been answered to their satisfaction. Those who consented to participate came to the research centre for a pre-selection visit when subject eligibility was determined by asking questions about medical history and drug use, measuring their height and weight, blood pressure, fasting plasma glucose and calculating the BMI. All subjects provided written informed consent prior to starting the study.

The protocol was approved by the Western Institutional Review Board which meets all the requirements of the US Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), the Canadian Health Protection Branch (HPB), Canadian Institutes of Health Research (CIHR) and the European Community Guidelines (IRB Tracking Number: 20183115).

Procedure for baking white bread

Bread was baked in a bread maker in loaves containing 500g available carbohydrate. The ingredients for each loaf (510 ml warm water, 694 g all-purpose flour, 14g sugar, 8g salt and 13g yeast) were placed into the bread maker according to instructions, and the machine turned on. After the loaf had been made, it was allowed to cool for an hour, and then weighed and after discarding the crust ends, the remainder was divided into portion sizes containing 50g or 35g available carbohydrate. These portions were frozen prior to use, and reheated in the microwave for 25 seconds, turned over and then heated for a further 25 seconds prior to consumption.