Glycemic Index Test Protocol Checklist

Instruction

Please complete all items below and attach document with submission form

Protocol Title……..
Principal investigator……

1. Participants

1.1 Number of healthy volunteer

[ ] Group of 5 for identical macronutrient composition but different flavors e.g. concentration of active ingredient
[ ] 10

If not as above, please state reason why…….

1.2 Exclusion criteria cover *ALL* of the followings:

- known food allergy or intolerance
- medications known to affect glucose tolerance
- a known history of diabetes mellitus or the use of antihyperglycaemic drugs or insulin to treat diabetes and related conditions
- a major medical or surgical event requiring hospitalization within the preceding 3 months;
- the presence of disease or drug(s) which influence digestion and absorption of nutrients;
- the use of steroids, protease inhibitors or antipsychotics (all of which have major effects on glucose metabolism and body fat distribution).

[ ] Cover all criteria
[ ] Not all. (Please state the reason……)

1.3 Test conditions requirement for participants

1. NOT take food or drink other than water for *10 h or more* prior to the test;
2. NOT taking alcohol on the previous evening;
3. NOT having vigorous exercise on the morning of the test.

[ ] ALL requirements are stated in protocol and participant information sheet
[ ] Not all (Please explain……)

2. Tested products

2.1 Reference food in the protocol

[ ] Glucose solution prepared from anhydrous glucose powder (50 g/250 ml water)
[ ] Prepare fresh
[ ] Stored in a refrigerator and used within 72 hours

[ ] Dextrose (glucose monohydrate, 55 g);
[ ] Commercial solution used for the oral glucose tolerance test containing glucose (50 g); (Please specify commercial source……)
[ ] White bread or other specific carbohydrate food of consistent composition and GI.

Please specify commercial source of reference food (……..)

2.2 The reference food is tested in each subject at least two or three times on separate days within the immediate 3 month-period

[ ] Yes
[ ] Two times [ ] Three times

[ ] No (Please explain…….)

2.3 Product to be tested for GI

2.3.1 Brief description……

Type of product

[ ] Commercial product in the market (Specify….)

[ ] Product under development

2.3.2 Detail of product and preparation for testing provided in separate document

[ ] Provided

[ ] Not provided (State the reason…..)

2.3.3 Carbohydrate portion of the test food

[ ] 50 g of glycaemic carbohydrate and consumable within the time frame of 12 min to 15 min

[ ] 25 g of glycaemic carbohydrate because the bulk of food providing 50 g is unreasonably large

[ ] Less than 10 g glycaemic carbohydrate per regular serving (This should not be tested for GI. If tested, state the reason why…….)

2.3.4 Test product prepared with milk

[ ] Yes (as milk may influences the final GI of some products, please state the reason why……)

[ ] No

3. Experimental procedure

3.1 Blood samples for 3.1.1 measuring fasting glucose [ ] Finger prick (prefer) [ ] Venous blood [ ] Two samples taken within 5 min. If not, please explain……. 3.1.2 GI Determination [ ] 6 samples shall be taken at 15 min, 30 min, 45 min, 60 min, 90 min, and 120 min [ ] More or less (Please explain……)
3.2 Taking food [ ] Within 12-15 min [ ] Other…….
3.3 Food preparation [ ] in 250-500 ml water [ ] in 250-500 ml coffee or tea (adding 30 ml milk and non-nutritive sweetener is acceptable)

4. Blood glucose analysis

4.1 Analytical method [ ] Spectrophotometry [ ] Electrochemical detection-coupled enzyme systems *Note: small glucometer devices used for self-blood glucose monitoring have published analytical CVs above 3,6 % and are therefore not suitable for GI testing*
4.2 Reference laboratory …….

This checklist is prepared by Office of Research Ethics, Research Institute for Health Science, CMU, using ISO 26642:2010(E) as the reference.