Long-term tolerance of different doses of NUTRIOSE®FB 06 in male adults

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INTRODUCTION

NUTRIOSE®FB 06 is a wheat starch based, weakly digested food dextrin, containing about 85% of soluble dietary fibres. In a previous study, it was demonstrated that NUTRIOSE®FB 06, when consumed for seven days, was well-tolerated up to a daily dose of 45g and that this product had fibre effects. The aim of the present study was to determine the gastro-intestinal tolerance of 30 and 45g of NUTRIOSE®FB 06 consumed by humans for 4-5 weeks, to study the long-term modification of colon microflora and to compare the results with consumption of the completely digested standard GLUCIDEX®6 maltodextrin.

MATERIALS AND METHODS

Subjects

- 48 healthy men
- Age 20-45 years
- BMI ≤31 kg/m²

Design

- Randomized study
- Placebo controlled
- Double blind
- 3 parallel treatments
- After a run-in period of one week, subjects consumed half the dose of study substance during the first week and then the full dose of study substance for four weeks
- The placebo group consumed 22.5g GLUCIDEX®6. The treated groups consumed 30 or 45g NUTRIOSE®FB 06 per day (the placebo group and the group treated with the greater amount of NUTRIOSE®FB 06 ingested the same energy content).
- Each dose was consumed in four equal portions at breakfast, morning, lunch and dinner for 28 days.
- Subjects restricted their fibre intake and excluded pre- and probiotics from their diet.

Study parameters

- Adverse events by daily well-being questionnaires and a diary.
- Faecal analyses: pH, microbiology, enzymatic activities, residue of NUTRIOSE®FB 06 estimated by polymerized glucose.
- Anthropometry: body weight, body composition by the bio-impedance method.

RESULTS AND DISCUSSION

Compliance

- The drop-out rate of the study was 10%, not, or unlikely to have been, related to the study treatment.

Digestive tolerance

- No serious adverse events occurred. The complaint "rumbling of the stomach" disappeared over time.
- No diarrhoea was reported.
- Both NUTRIOSE®FB 06 dosages were well tolerated.

Faecal analyses (Fig. 1)

- Faecal pH decreased after three weeks time and treatment from 6.5-6.6 (all treatments at the start of the study) to 6.1 for both NUTRIOSE®FB 06 treatments at day 35 (the end of the study).
- Total glucosidases (α and β) increased significantly with NUTRIOSE®FB 06 treatments.
- Data showed an increase in Lactobacilli for day 35 versus day -1 for 45g (7.2 vs 8.2 log cfu/g faeces) on NUTRIOSE®FB 06 treatment and a trend towards a lower number of Clostridia (5.9 vs 5.6 log cfu/g faeces).

Anthropometry (Table I)

- Body weight in both NUTRIOSE®FB 06 groups remained stable, whereas the reference group showed a small increase. Although no significant difference was found (p=0.07), the trend is a promising result because of the shortness of the treatment period.

Fig. 1: Faecal parameters following 35 days consumption of NUTRIOSE®FB 06 or placebo

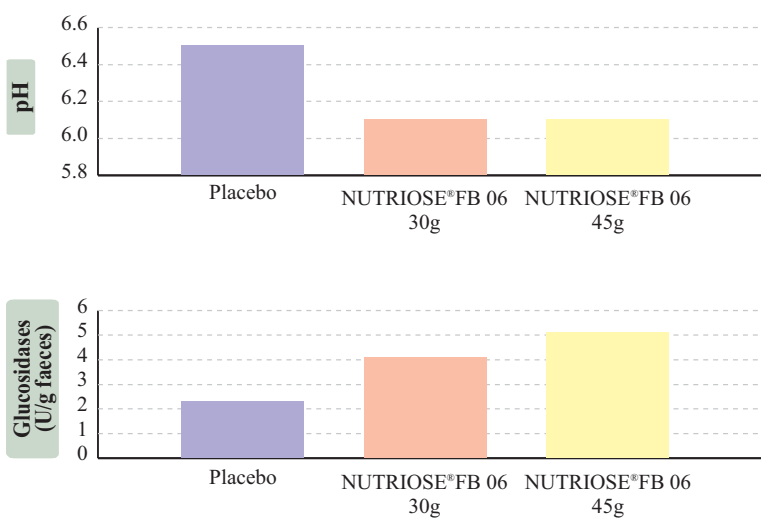

Table I: Mean body weight (kg) at the first and last day of the study

Treatment	***Placebo***	***NUTRIOSE®FB 06 30g***	***NUTRIOSE®FB 06 45g***
Day -1	80.4 ± 11.8	82.1 ± 12.0	86.0 ± 12.9
Day 35	81.2 ± 11.9	82.1 ± 11.6	86.0 ± 12.6
Difference	**0.8**	**0.0**	**0.0**

CONCLUSION

The dietary fibre NUTRIOSE®FB 06 is a fermentable carbohydrate, **well tolerated in the long-term at 30-45g daily.**
No negative effects were found on gastrointestinal parameters.

The product was well fermented, which resulted in an increase in Lactobacilli and α - β glucosidases and a decrease in the faecal pH.
A trend in decrease of Clostridia was also observed.

We also observed a trend towards better weight maintenance with the dietary fibre NUTRIOSE®FB 06, which is promising.

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