CHRONIC TREATMENT STUDIES

<table>
<thead>
<tr>
<th>Type</th>
<th>Reference</th>
<th>Title</th>
<th>Fiberol dose (source)</th>
<th>Treatment Duration</th>
<th>Age of Participants</th>
<th>Qualifying Parameters</th>
<th>Study Design</th>
<th>N/group</th>
<th>Observed variables</th>
<th>Result(s)</th>
<th>significance</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Fujisawa et al 1999 J Jpn Clin Nutr 83(3):301-305</td>
<td>Continuous administration tests of indigestible dextrin; II study on the effects of the improvement of fat metabolism in patients with non-insulin-dependent diabetes mellitus</td>
<td>30 g/d (10 g indigestible dextrin with meals 3x/d) dissolved in 100 ml water (potato starch)</td>
<td>16 weeks</td>
<td>54.8 yrs (41-68)</td>
<td>insulin resistant diabetics (NIDDM)</td>
<td>uncontrolled study</td>
<td>5</td>
<td>body weight, blood pressure, and blood and urine collected at baseline, and then at weeks 4, 8, 12, and 16</td>
<td>Significant decreases in triglyceride and B-lipoprotein levels (P&lt;0.05) compared to baseline values. No significant changes in total cholesterol or HDL cholesterol.</td>
<td></td>
<td>Uncontrolled study; and 4 of the 5 patients were taking an oral hypoglycemic drug (Glibenclamide). Two of the subjects also had complications of hypertension, 3 patients with hyperlipidemia, and 2 with fatty liver disease.</td>
</tr>
<tr>
<td>2</td>
<td>Fukuda et al 2002 J. Nutr. Food 5(21-29)</td>
<td>Effect of green tea beverage containing indigestible dextrin on the suppression of postprandial blood glucose elevation and the safety of its long-term use</td>
<td>20.1g indigestible dextrin PF-C* (8.7g/serving 3x/d)</td>
<td>12 weeks</td>
<td>?</td>
<td>healthy subjects</td>
<td>uncontrolled study</td>
<td>18</td>
<td>physical measurements, serum cholesterol, serum chemistry and CBC</td>
<td>No changes in triglycerides, total cholesterol, or HDL cholesterol. The changes in triglycerides were in a normal range, but did tend to decrease from baseline (105 mg/dl to 89.9 mg/dl at 12 weeks) but this was not statistically significant.</td>
<td></td>
<td>Uncontrolled study.</td>
</tr>
<tr>
<td>3</td>
<td>Fukushima et al 2002 J Nutr. Food 5(3), 109-116</td>
<td>Effects of blend tea containing indigestible dextrin on post-prandial blood glucose level and safety of long-term administration</td>
<td>15g indigestible dextrin* (190g serving of blend tea with 5g indigestible dextrin 3x/d with meals)</td>
<td>12 weeks</td>
<td>33.4+1.8yrs</td>
<td>healthy male subjects</td>
<td>uncontrolled study</td>
<td>9</td>
<td>Anthropometric measures; ht., wt., waist, hip, body fat, blood pressure, pulse rate; Clinical exam; blood chemistry including serum lipids, liver function, kidney function, electrolytes, fat metabolism, sugar metabolism, and urine</td>
<td>Tg levels were not significantly changed from baseline. No change in total cholesterol, LDL cholesterol. There was a significant but modest decrease in HDL at 13 weeks compared to baseline (p&lt;0.05).</td>
<td></td>
<td>Small sample size, uncontrolled study.</td>
</tr>
<tr>
<td>4</td>
<td>Fuse et al 2002 J of Nutr. Food 5(4), p47-53</td>
<td>Effect of cooked rice containing indigestible dextrin on the suppression of postprandial blood glucose level and the safety of eating it in long term in</td>
<td>Semi-aseptic packaged rice containing (total dietary fiber =7.5g). 6.8g indigestible dextrin (PineFibre-C)* 3 times per day 20-April</td>
<td>12 weeks</td>
<td>40.3±8.2</td>
<td>healthy male subjects</td>
<td>uncontrolled study</td>
<td>10</td>
<td>physical measurements, serum cholesterol, serum chemistry and CBC</td>
<td>No changes in total cholesterol, HDL, or triglycerides. There was a decrease from baseline which was not significant for the triglycerides (148.5 to 131.9 mg/dl) there was no indication in the text that there were statistical comparisons made from baseline.</td>
<td></td>
<td>Uncontrolled study with limited subjects.</td>
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<tr>
<td>5</td>
<td>Hori et al 2005 J. Nutr. Food 8(3) 27-35</td>
<td>Effect of black tea containing indigestible dextrin on postprandial blood glucose level and safety of long-term administration</td>
<td>18.6 g Fibersol-2* (6.2g Fibersol-2* and powdered black tea extract in 150ml warm water, taken 3x/d with meals)</td>
<td>12 weeks</td>
<td>NA</td>
<td>Healthy subjects</td>
<td>uncontrolled study</td>
<td>15</td>
<td>physical measurements, serum cholesterol, serum chemistry and CBC, gastrointestinal observations</td>
<td>There was a significant reduction in serum total Cholesterol after 12 weeks of treatment compared to baseline (p&lt;0.001). LDL cholesterol also tended to decrease however did not reach statistical significance. There was no significant change in triglycerides.</td>
<td></td>
<td>Uncontrolled study.</td>
</tr>
<tr>
<td>6</td>
<td>Ikeuchi et al 2006 J of Jpn Council for Advanced Food Ingredients Research 9(1) 57-64</td>
<td>Effects of soup powder containing indigestible dextrin and young barley leaf powder on postprandial blood glucose level</td>
<td>15.3 g indigestible dextrin* (3 servings/g of 5.1 g in soup)</td>
<td>12 weeks</td>
<td>37.1±9.4</td>
<td>Healthy adults</td>
<td>uncontrolled study</td>
<td>15</td>
<td>Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks</td>
<td>No changes in triglycerides, total cholesterol, LDL, or HDL cholesterol. LDL cholesterol was statistically lower from baseline (p&lt;0.05) at 12 weeks.</td>
<td></td>
<td>Uncontrolled study.</td>
</tr>
<tr>
<td>7</td>
<td>Inoue et al 2005 J. Japan Clinical Nutr. 26(4):281-286</td>
<td>Attenuation effect of bread containing indigestible dextrin on elevation of postprandial blood glucose level and its safety in long-term ingestion</td>
<td>8g Fibersol-2* (4g = 2x/d)</td>
<td>12 weeks</td>
<td>33.6±5.8 yr</td>
<td>healthy adults</td>
<td>uncontrolled study</td>
<td>17</td>
<td>physical measurements, serum cholesterol, serum chemistry and CBC</td>
<td>No changes in triglycerides, total cholesterol, LDL or HDL cholesterol.</td>
<td></td>
<td>Uncontrolled study.</td>
</tr>
<tr>
<td>8</td>
<td>Ito et al 2006 Jpn Pharmacol Ther 34(8) 945-952</td>
<td>Effects of powdered drink containing indigestible dextrin and young barley leaf powder on postprandial blood glucose level</td>
<td>15.3 g Fibersol®* (3 servings/g of 5.1 g in 100ml green tea)</td>
<td>12 weeks</td>
<td>?</td>
<td>10 Healthy adults and 5 subjects with slightly high fasting blood glucose levels.</td>
<td>uncontrolled study</td>
<td>15</td>
<td>Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks</td>
<td>There was a significant reduction in serum total Cholesterol after 12 weeks of treatment compared to baseline. There was also a trend for decreases in total cholesterol. There was no significant change in triglycerides, although they did tend to</td>
<td></td>
<td>Uncontrolled study.</td>
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<tr>
<td>9</td>
<td>Kajimoto et al 2000 J Nutritional Food 3(3): 47-58</td>
<td>Beneficial effects of a new indigestible dextrin-containing beverage on lipid metabolism and obesity-related parameters</td>
<td>16.5 g (in a 250 ml test drink, 3 times per day 5.5 g indigestible dextrin per bottle)*</td>
<td>4 weeks</td>
<td>35±10.4 yrs</td>
<td>mixed hypertiglyceridemic men (150-250 mg TG/dl)</td>
<td>Randomized, placebo controlled study</td>
<td>10=8placebo 2placebo</td>
<td>Physiologic examination and serum tested before run in, after 2 week run in(baseline), after 4 weeks of treatment, and then after 2 weeks of wash out</td>
<td>TG levels were significantly reduced compared to placebo (p=0.026). Cholesterol also tended to be lower (p=0.05) compared to control after 4 weeks of treatment. There were also decreases in B- lipoprotein.</td>
<td></td>
<td>Uncontrolled study.</td>
</tr>
<tr>
<td>Study ID</td>
<td>Study Design</td>
<td>Subject Information</td>
<td>Intake Details</td>
<td>Outcome Measures</td>
<td>Results</td>
<td></td>
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<td>10</td>
<td>Effects of a tea beverage containing indigestible dextrin on the serum triglyceride levels in subjects with mild hyperglyceremia</td>
<td>18.3 g indigestible dextrin (PinFiber-C*)</td>
<td>12 weeks</td>
<td>Men, placebo controlled, double blind study</td>
<td>No changes in triglycerides, total cholesterol, or HDL cholesterol.</td>
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<td>11</td>
<td>Safety of a long-term intake of a tea beverage containing indigestible dextrin</td>
<td>5.8 yr Healthy Subjects</td>
<td>Uncontrolled study</td>
<td>Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks</td>
<td>No changes in triglycerides, total cholesterol, or HDL cholesterol.</td>
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<tr>
<td>12</td>
<td>Safety of intake of Inositol</td>
<td>8.2 yr Healthy Subjects</td>
<td>Uncontrolled study</td>
<td>Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks</td>
<td>No changes in triglycerides, total cholesterol, or HDL cholesterol.</td>
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</tbody>
</table>

**Notes:**
- *PinFiber-C* contained in 160 ml of miso soup
- *FF-C* (4.4 g PF-C contains 44 mg of indigestible dextrin)
- *PF-C* (5.9 g PF-C contains 160 mg of indigestible dextrin)
- *FF-C* contained in 160 ml of miso soup
- *PF-C* contained in 160 ml of miso soup

**Serum Lipids:**
- Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks
- No changes in triglycerides, total cholesterol, or HDL cholesterol.
Effect of intake of Freeze-dried tomato soup containing indigestible dextrin on their long-term intake.


19 I

13.2 g indigestible dextrin* (PineFiber-C) (4.4 g/serving of harusame (noodle) soup (15.5 g serving; 44 kcal) taken 3x/d) 12 weeks 31.8 ± 5.3 Healthy Adults uncontrolled study Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks No changes in triglycerides, total cholesterol, or HDL cholesterol. uncontrolled study with limited subjects


20 I

Efficacy of tea drink containing indigestible dextrin

18.75 g/d (2.5 g of indigestible dextrin (PF-C) in 190 g serving of tea meal)* 12 weeks 36.4 ±11.9 yrs healthy subjects with slightly elevated blood glucose level or family history of diabetes uncontrolled study fasted blood sample for serum measures of lipids, chen 21 panel, and blood glucose taken at 4 week intervals


21 I

Effects of instant miso-soup containing indigestible dextrin on moderating the rise of postprandial glucose levels and safety of long-term administration

13 g indigestible dextrin (PF-C) in miso-soup/meal x 3/d)* 12 weeks 40.8 ±3.3 yrs hyperglycemic subjects uncontrolled study fasted blood sample for serum measures of lipids, chen 21 panel, CBC and blood glucose taken at 4 week intervals


22 I

Effects of along-term administration of indigestible dextrin

30g Fiberol-2* (10 g indigestible dextrin with meals 3/d) dissolved in water (corn starch based) 12 weeks 46.1 ± 3.0 yrs total serum cholesterol level ≥220 mg/dl or TG ≥150 mg/dl (all men) uncontrolled study fasted blood sample for serum measures of lipids, chen 21 panel, and blood glucose taken at baseline and 12 week end point, 9/12 participants also had an abdominal CT


23 I

The effects of tea beverages containing indigestible dextrin on postprandial blood glucose level after single intake and safety in continuous intake

18.9g Fiberol-2* (5g/serving in blended tea beverage taken 3x/d) 12 week 39.1±9.2 Healthy Subjects uncontrolled study Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks No changes in free fatty acids, triglycerides, total cholesterol, or HDL cholesterol. uncontrolled study with limited subjects


24 I

Continuous administration of indigestible dextrin: I: a study on the effects of the improvement of fat metabolism in healthy volunteers

30 g (10 g indigestible dextrin with meals 3/d) dissolved in 100 ml water * 4 weeks (2 subjects continued to 8 weeks at this dose, while 8 subjects received half the daily dose) 50.3 yrs (33-59) healthy subjects uncontrolled study fasted blood sample for serum measures of lipids, chen 21 panel, CBC and blood glucose taken at baseline and 4 weeks

Mizushima et al. 2000 J. Nutritional Food 3(2): 75-82

25 I

Effect of long-term ingestion of indigestible dextrin-containing soft drinks on safety and blood lipid levels

29.4 g (9.8 g of PF-C/100 ml soft drink)* 12 weeks 44.4 ±6.9 yrs borderline hyperglycemic male subjects (fasting blood glucose >10 mg/dl ≥126 mg/dl) uncontrolled study blood tests, UA, and health checks at 0, 4, 8, 12 weeks during treatment and then again post-treatment after 8 weeks


26 I

The effect of the intake of green tea beverage containing indigestible dextrin on postprandial glucose level and the investigation of the safety as its long-term intake

21.6g Fiberol-2* in yogurt (7.2g Fiberol-2/serving taken 3x/d) 12 weeks 34.0±6.3 Healthy Subjects uncontrolled study Blood samples taken at 0, 4, 8, and 12 weeks No changes in triglycerides, total cholesterol, LDL or HDL cholesterol. Uncontrolled Study


27 I

Effects of Long-term Administration of Indigestible Dextrin as Soluble Dietary Fiber on lipid and glucose metabolism

15.3g of indigestible dextrin (PF-C)* (5.1 g/serving taken 3x/d) 12 weeks 36.0 ± 10.3y Healthy Subjects uncontrolled study Blood and Urine tests before intake and after 4, 8, and 12 weeks No changes in triglycerides, total cholesterol, LDL or HDL cholesterol. uncontrolled study


28 I

Efficacy of packed boiled rice containing indigestible dextrin on moderating the rise of postprandial glucose levels, and safety of long-term administration

12.6 g indigestible dextrin* (6 g/serving of 200g boiled rice) 12 weeks 35 ± 8.4 healthy subjects uncontrolled study blood glucose levels and other clinical serum measures at baseline, 6 and 12 weeks


29 I

Overall there was no effect on total cholesterol, LDL, or Triglycerides at either 6 or 12 weeks compared to baseline. Serum triglycerides decreased with time in one subject.

Serum Lipids
The inhibitory effect on the postprandial increase in blood glucose exerted by a powdered beverage containing indigestible dextrin and its safety in long-term ingestion

<table>
<thead>
<tr>
<th>Study</th>
<th>Reference</th>
<th>Treatment</th>
<th>Age of Participants</th>
<th>Qualifying Parameters</th>
<th>Study Design</th>
<th>N/group</th>
<th>Observed variables</th>
<th>Result(s)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>Shoya et al 2004 J. of Nutr. Food 4(4) 31-41</td>
<td>24.6 g Fibersol-2 (8.2 g Fibersol-2 in powdered beverage dissolved in 100 ml water taken 3 x/d)</td>
<td>12 weeks</td>
<td>Healthy Subjects</td>
<td>uncontrolled study</td>
<td>19</td>
<td>Clinical, hematological, biochemistry, and urinary exams at 4, 8, and 12 weeks</td>
<td>Total cholesterol decreased significantly from baseline at 12 weeks, however HDL cholesterol also decreased significantly from baseline at 12 weeks and accounts for some of the change in total cholesterol.</td>
<td>Uncontrolled study - Beverage contained 8.2 g Fibersol, 0.25 g Grifola frondosa, 0.15 g powdered plum extract, and 1.46 g lactose.</td>
</tr>
<tr>
<td>31</td>
<td>Suzuki et al 2001 J. of Nutr. Food 4(4) 71-78</td>
<td>15 g/d indigestible dextrin (PF-C)* in a powdered tea beverage (5 g/serving taken 3 x/d)</td>
<td>12 weeks</td>
<td>Healthy subjects</td>
<td>uncontrolled study</td>
<td>6 female</td>
<td>No changes in triglycerides, total cholesterol, or HDL cholesterol.</td>
<td>Uncontrolled study</td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>Takeyasu et al 2006 Jpn Innovative Food Ingredients Research 9(1) 37-45</td>
<td>18.6 g/d PineFiber-C* (taken in 3 servings of 6.2 g PF-C in cooked rice (200 g/serving)</td>
<td>12 weeks</td>
<td>Healthy Adults-fasting blood glucose&lt;126 mg/dl</td>
<td>uncontrolled study</td>
<td>16</td>
<td>Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks</td>
<td>No changes in triglycerides, total cholesterol, LDL or HDL cholesterol.</td>
<td>Uncontrolled study</td>
</tr>
<tr>
<td>33</td>
<td>Tamura 2003 J. of Nutr. Food 6(3) 55-63</td>
<td>A green tea powder containing indigestible dextrin: In its intake effect on postprandial blood glucose level and the safety of long-term ingestion.</td>
<td>12 weeks</td>
<td>2 Healthy Subjects and 8 subjects who had higher postprandial blood glucose levels</td>
<td>uncontrolled study</td>
<td>10</td>
<td>Fasting blood samples and physical exams at 0, 4, 8, and 12 weeks</td>
<td>No changes in free fatty acids, triglycerides, total cholesterol, or HDL cholesterol.</td>
<td>Uncontrolled study</td>
</tr>
<tr>
<td>34</td>
<td>Tokunaga and Matsuoka 1999 J. Japan Diab Soc: 42 (1): 61-65</td>
<td>Effects of a FOS/HU (food for specific health use) containing indigestible dextrin on postprandial levels of blood glucose and fat metabolisms</td>
<td>12 weeks</td>
<td>48.3 ± 3.4 yrs</td>
<td>healthy subjects</td>
<td>uncontrolled study</td>
<td>Fasting blood sample for serum measures of lipids, then 21 panel, and blood glucose.</td>
<td>No significant improvements in total cholesterol or HDL cholesterol compared to baseline. TG levels decreased in all subjects compared with baseline levels (P&lt;0.05). No LDL measured.</td>
<td>Small number of subjects, and no control group.</td>
</tr>
</tbody>
</table>

Serum Lipids

<table>
<thead>
<tr>
<th>Type</th>
<th>Reference</th>
<th>Fibersol dose (source)</th>
<th>Treatment</th>
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<th>Study Design</th>
<th>N/group</th>
<th>Observed variables</th>
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<th>Significance</th>
<th>Comments</th>
</tr>
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</table>

24/36 of these studies were done in normal healthy subjects without indication of problems associated with cholesterol. 2/36 of the studies had a control group, all others were uncontrolled.
Kishimoto et al. 2007 Eur J Nutr

Suppressive effect of resistant maltodextrin on postprandial blood triacylglycerol elevation. 5 or 10 g of Fibersol in 350 ml carbonated beverage (Cornstarch) Single meal containing 50 g of fat, and treatment beverage 36.5 ± 2.8 yrs 13 healthy adults (11 males, 2 females) single blind cross-over study (1 week wash out) 13

Acute study, blood collected at 0.5, 1, 2, 3, 4, 5, and 8 hr postprandially after consumption of loading meal and beverage. Triglycerides were significantly lower for several time points compared to control and AUC for the treatments were also significantly lower than control. There were some significant differences in cholesterol at specific time points in the Fibersol treated groups compared to control. Cholesterol AUC tended to decrease compared to control, but no significant differences were seen.

Loading Meal: Commercial hamburger and 135 g of fried potatoes. Only a post-prandial assessment. This in acute study only and thus was graded low, as it does not provide evidence on long term studies. However it does still provide insight into the mechanisms by which Fibersol may impact triglyceride levels.

Acute Study