Reporting of Clinical Trial Results: GINST

Ginseng Research Institute

2010. 02. 22.

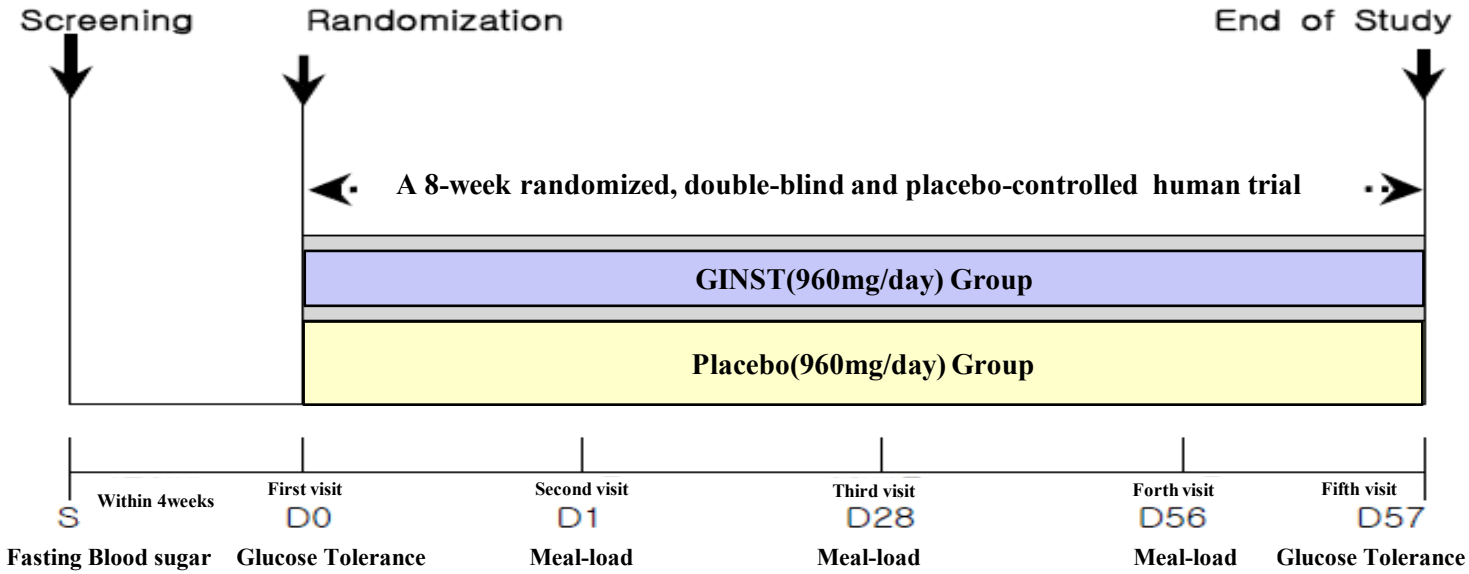
Clinical Study Designs

Official Title	An 8-week randomized, double-blind human trial to compare the efficacy and safety of GINST and placebo on improvement of glycemia
Objectives	Primary: To assess the effectiveness and safety of "GINST" effect on glucose level control assessed by FPG and PPG level change data. Secondary: To assess the effectiveness and safety of "GINST" about change of insulin(fasting plasma insulin <FPI>, postprandial insulin <PPI>), HbA1c, glycated albumin, fructosamine, total cholesterol, LDL, HDL-cholesterol and triglyceride.
Conducting Institute/ Lead Researcher	ChonBok National University Hospital Clinical Trial Center ChonBok National University Department of Laboratory Medicine, Professor D.C. Kim.
Study Researcher	ChonBok National University Hospital Clinical Trial Center S.Y. Kimm H.Y. Back, J.Y. Jun, M.H. Kim, S.H. Park, M.R. Oh, S.M. Han, M.J. Lee, B.L. Kim, J.H. Shin, S.K.Choi, J.H. Lee, M.J. Cho, J.Y. Yang, Y.H. Choi

Clinical Trial design and Methods

Experimental Protocol

Randomized, double-blind, placebo human trail.
Volunteers are treated with either GINST(960 mg/day) or placebo(960 mg/day) throughout the screening for 4-weeks.
Subjects are evaluated with inclusion/exclusion criteria at screening visits.
Subjects are recruited and randomized.
Baseline studies were completed before first treatment at the second visit.



Clinical Trial design and Methods

Intervention

GINST – Oral treatment two times per day 40 min before breakfast and dinner (480 mg/1time, 960 mg/1day)
Placebo - Oral treatment two times per day 40 min before breakfast and dinner (480 mg/1time, 960 mg/1day)

Evaluation Criteria /Method

Effectiveness Evaluation
1) Primary Effectiveness Data
The change between Postprandial glucose(PPG) after(15, 30, 60, 90 and 120 min) consuming a standard meal and change of fasting glucose level between visits.
2) Secondary Effective Data
The change in fasting plasma insulin <FPI>, postprandial insulin <PPI>), HbA1c, glycated albumin, fructosamine, total cholesterol, LDL, HDL-cholesterol and triglyceride between visits
Product compliance safety assessment
1) Adverse reactions, Laboratory medical results, Vital sign and Checkup

Statistical analysis

Primary effectiveness evaluation
paired t-test, T-test
Secondary effective evaluation
T-test, Chi-square test
Rate of subjects who had adverse reactions were summarized and provided in double-blind test groups during human trial. The list of subjects out of normal range is also reported.

Results

Results

1. The primary outcome

① First · fifth visit (75-g Oral Glucose Tolerance Test(OGTT))

Glucose level decreased in GINST group and increased in placebo group.

It indicated statistically significant differences especially in changes of fasting plasma glucose level before(40min, p=0.002) dietary supplement and just before consuming glucose drink(0min, p=0.021) and also in postprandial glucose after 30min(p=0.024) and 60min(p<0.001) between the treatment groups.

② Second · third · forth visit(meal-load)

Blood sugar level is decreased in GINST group and increased in placebo group

It indicates statistically significant differences especially in changing of fasting plasma glucose (p<0.001) and postprandial glucose after 30min(p=0.002) and after 60min(p=0.018) between the treatment groups.

2. The secondary outcome

① First · fifth visit

It shows statistically significant differences(p=0.045) between administered groups by increasing the insulin level right before consuming glucose drink(0min) in placebo group.

② Second · third · forth visit

The concentration of fasting insulin and after meal insulin, glycated albumin, fructosamin, total cholesterol, triglyceride, LDL-cholesterol, HbA1c did not showed any significant differences before and after 4· 8 weeks human trial product treatment in groups.

HDL-cholesterol indicated likely decrease in GINST group. Changes showed statistically significant difference between treatment groups(p=0.032).

Results

Results

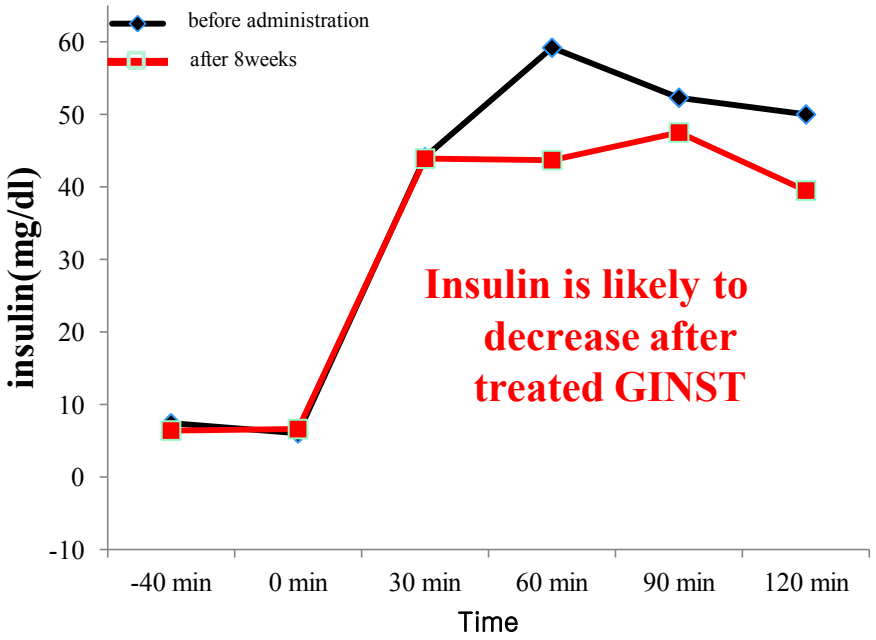
3. Stability trial results

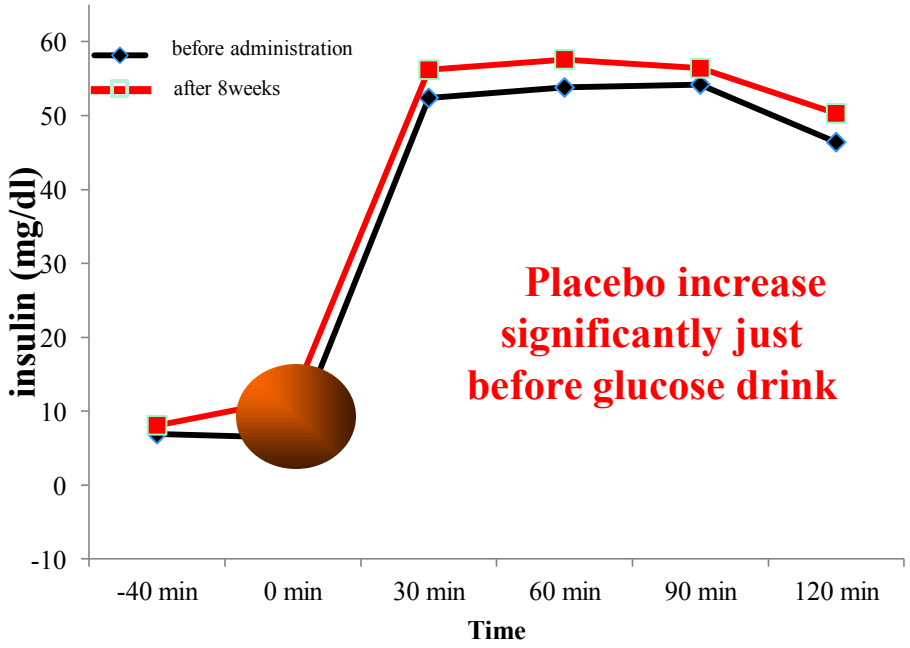
Among 60 different consumed human trial treatment, adverse events were reported during the intervention. But the number of adverse event subjects and occurrences is not significantly different between the groups.

The results of laboratory medical , checkup, vital sign and ECG did not show any meaningful change clinically before and after the 4· 8 weeks human trial product treatment.

Oral Glucose Tolerance Results (OGTT) - Insulin

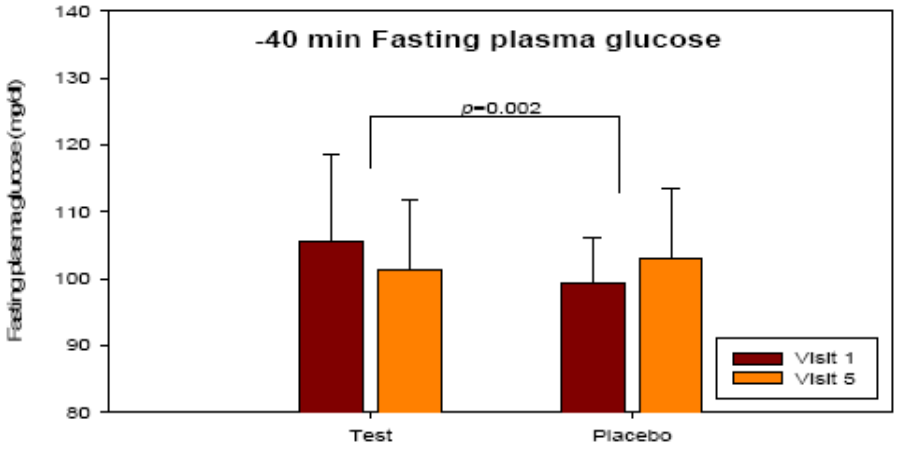
Insulin is likely to decrease in GINST and increase in placebo after glucose drink during OGT Test

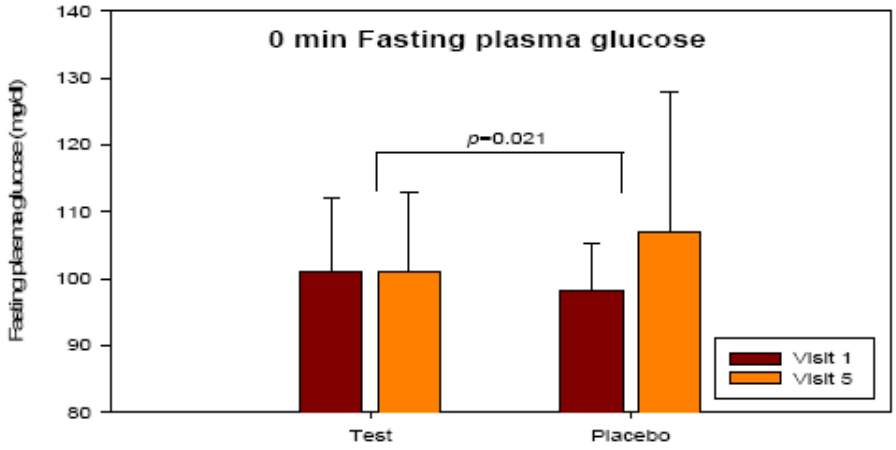


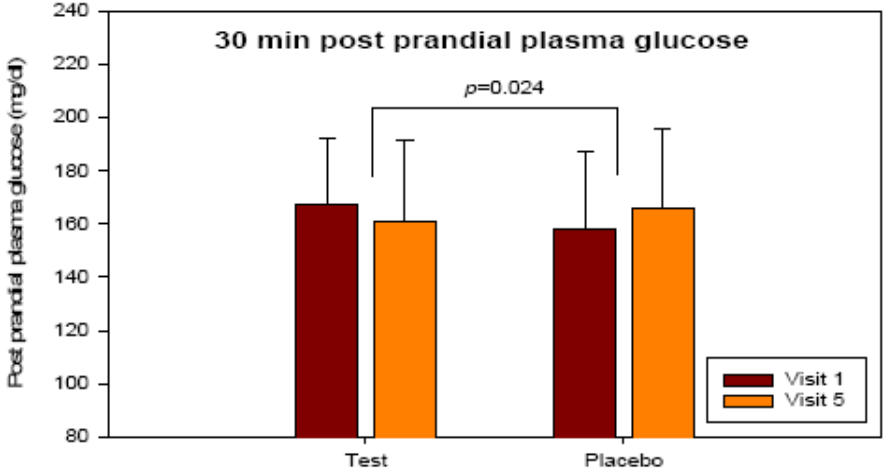


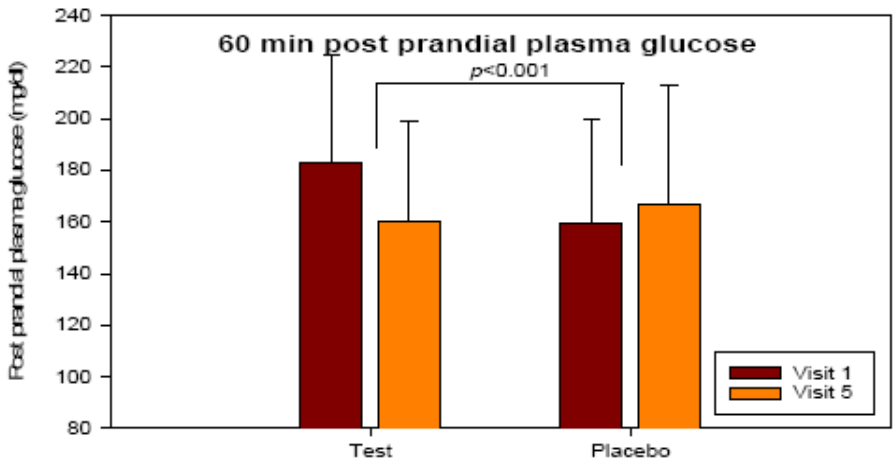
OGTT Results - glucose levels

Glucose levels decrease significantly at before (-40 min and 0 min)and after (30 and 60 min) consuming a glucose drink in GINST compared to placebo during OGT test



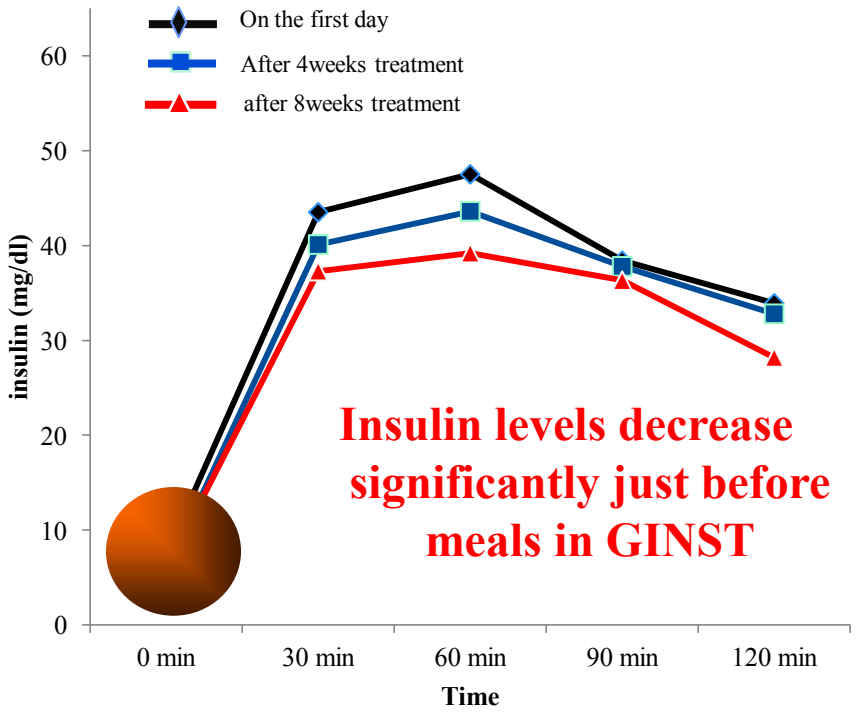


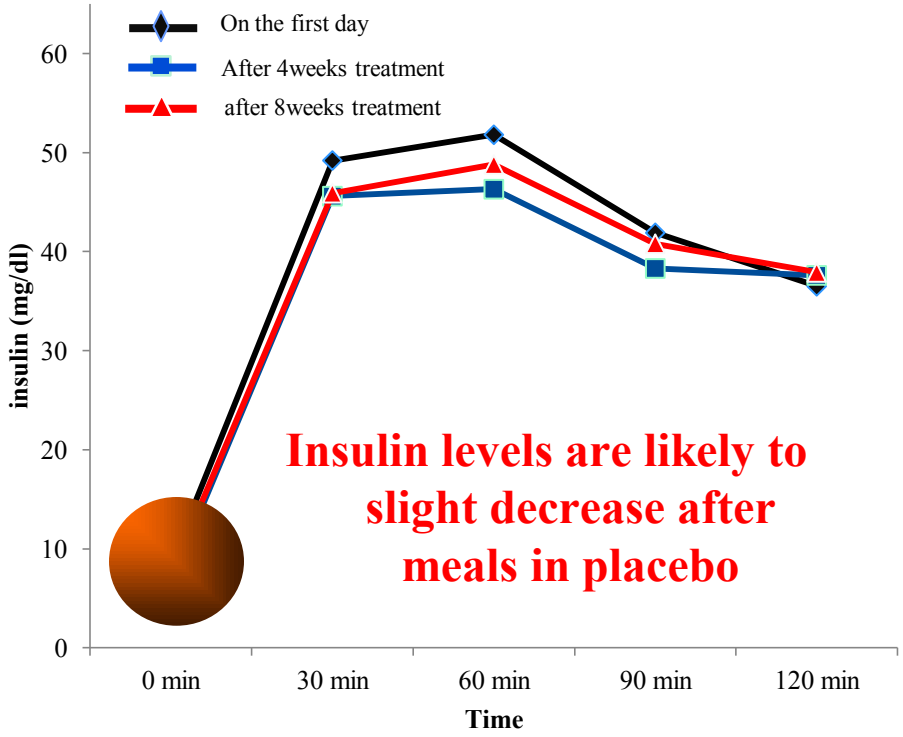




Results – Postprandial insulin test

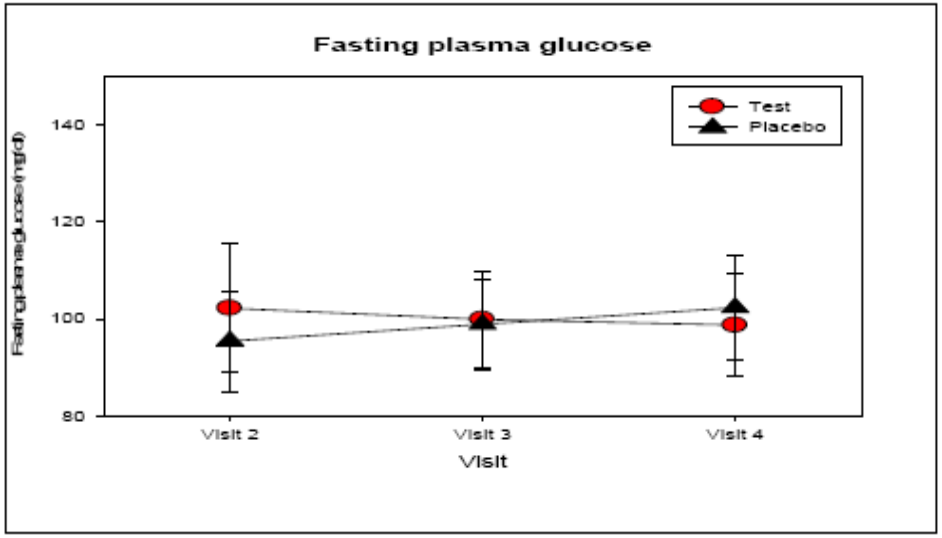
Postprandial insulin is likely to decrease in both GINST and placebo at postprandial insulin test but no difference between two groups

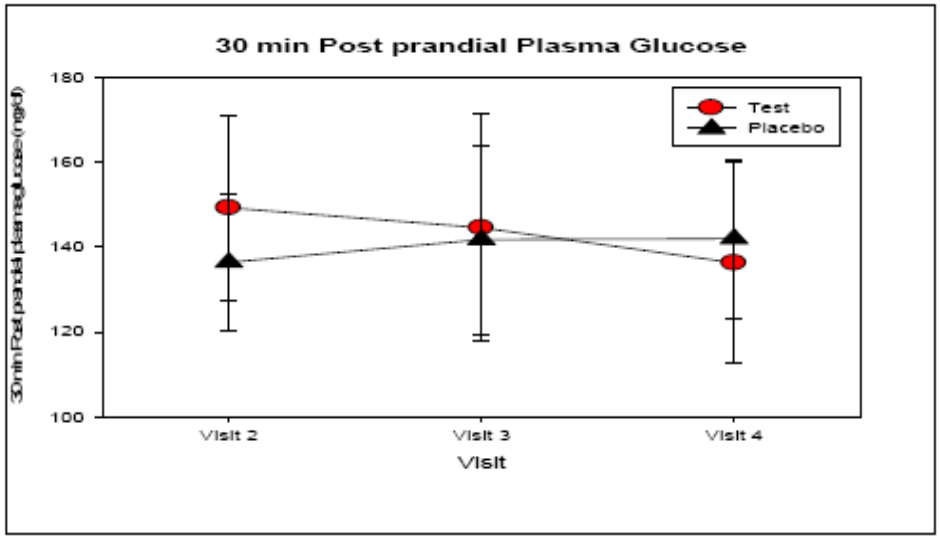


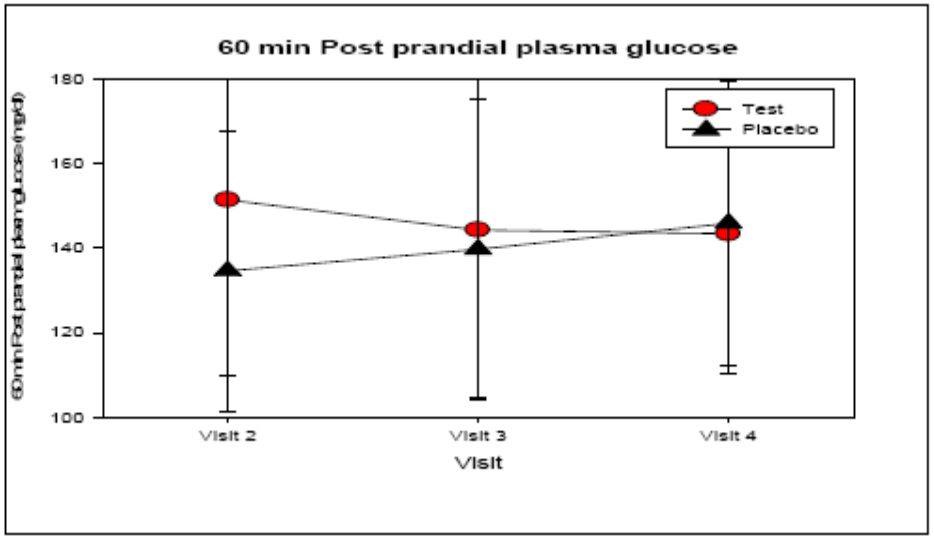


Results – Postprandial glucose levels

Glucose levels decrease significantly at fasting and after 30, 60 min meal in GINST compared to placebo

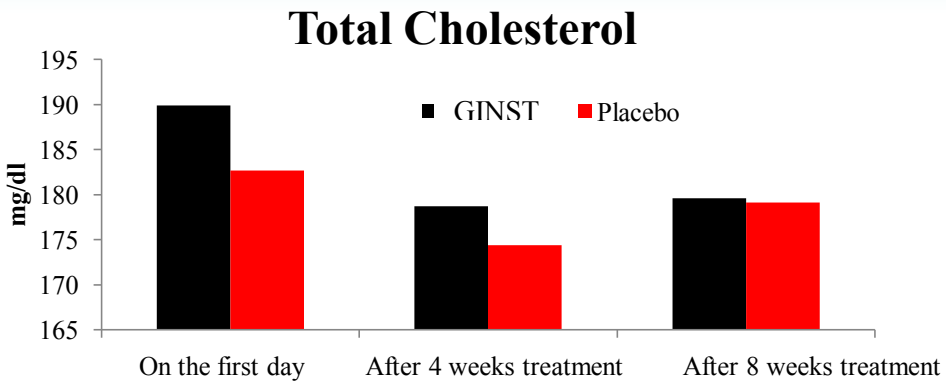


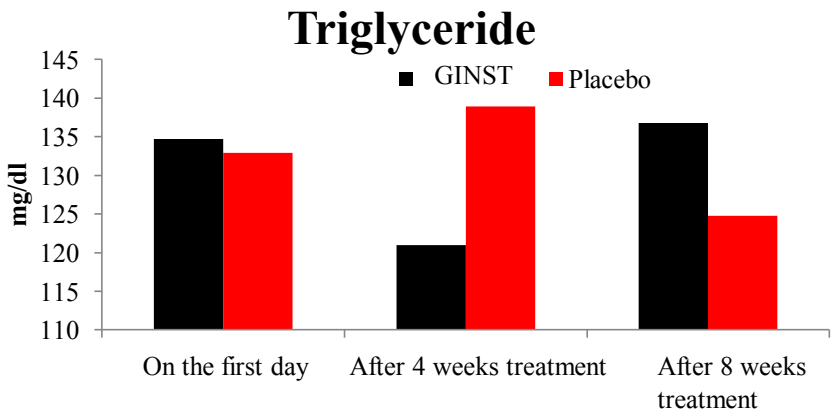


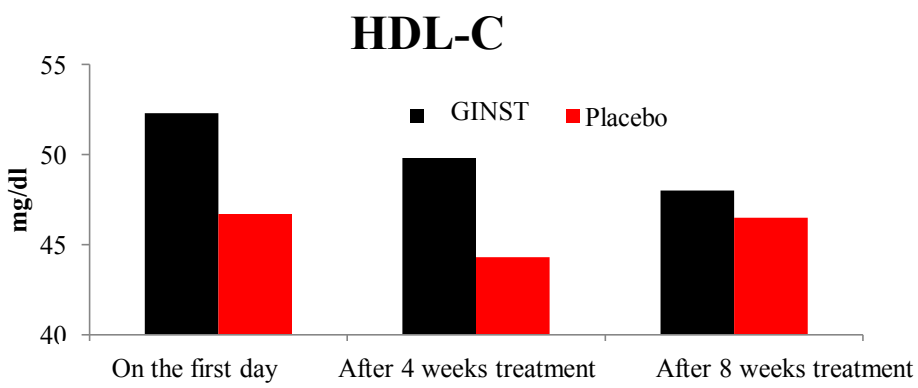


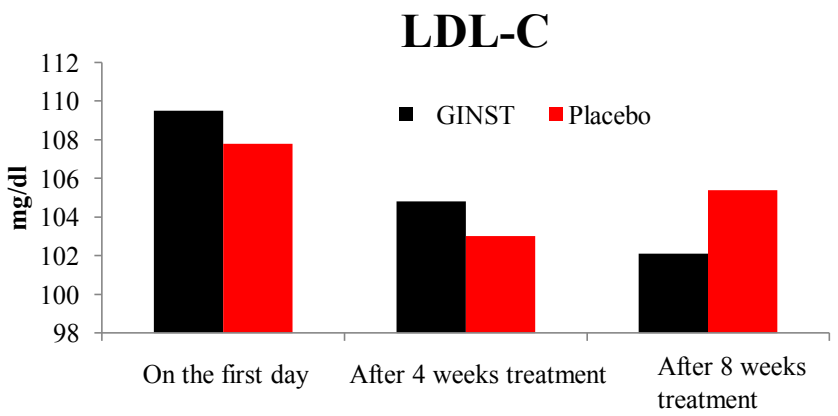
Clinical Result- Lipid blood test after a meal

Total cholesterol and LDL- C decrease significantly after a meal in GINST group during lipid blood test (all normal ranges)









Conclusions

1. Fasting glucose level

Fasting glucose levels are more likely to decrease in GINST groups and increase in placebo groups.

2. Postprandial glucose level

Postprandial glucose level is more likely to decrease in GINST groups and increase in placebo groups.

3. The relative index of glucose level

There were no significant differences between the treatment groups in fasting plasma insulin levels, postprandial insulin levels, glycated albumin, frctosamine, total cholesterol, triglyceride, LDL- cholesterol, HbA1c.

HDL- cholesterol indicates likely decrease in the GINST group.

GINST demonstrates glucose control function by decreasing fasting glucose levels and glucose level after 30, 60min meals significantly.

Also, no adverse events or changes were reported(considered clinically significant), so there are no safety issues.

Ilhwa Human Trial Statistics Analysis Supplementary Data

A 8-week randomized, double-blind human trial
to compare the efficacy and safety of GINST and placebo
on improvement of glycaemia

2011. 09. 22.

1. Meal-load

Table 1. Fasting plasma glucose and postprandial plasma glucose – revision of early stage fasting glucose, compare between two groups during the secondary visit

			Test group (n=29)	Placebo group (n=28)	*P*-value[1)]
Blood glucose (mg/dl)	Fasting Plasma Glucose		100.00 ± 0.00	100.00 ± 0.00	-
	Postprandial plasma glucose	15 min	105.21 ± 8.13	109.38 ± 10.47	0.098
		30 min	146.51 ± 16.18	143.43 ± 12.5	0.425
		60 min	146.72 ± 28.03	140.49 ± 27.54	0.401
		90 min	129.91 ± 25.22	131.36 ± 31.96	0.850
		120 min	124.09 ± 23.09	124.25 ± 24.71	0.980
	Total AUC (mg*min/dl)		15785.13 ± 2076.05	15637.14 ± 2198.03	0.795

Values are presented as mean ± SD

1) Independent t-test

Table2 . Fasting plasma glucose and postprandial plasma glucose – revision of early stage fasting glucose, compare between two groups during the third visit

			Test group (n=29)	Placebo group (n=28)	*P*-value[1)]
Blood glucose (mg/dl)	Fasting Plasma Glucose		98.49 ± 10.33	104.38 ± 10.23	0.035*
	Postprandial plasma glucose	15 min	106.78 ± 14.42	111.07 ± 14.54	0.268
		30 min	142.08 ± 23.98	149.38 ± 22.96	0.246
		60 min	141.27 ± 35.09	146.45 ± 34.32	0.576
		90 min	130.40 ± 29.57	133.64 ± 38.40	0.722
		120 min	121.04 ± 22.04	128.30 ± 32.29	0.325
	Total AUC (mg*min/dl)		15503.06 ± 2732.08	16137.04 ± 3089.14	0.415

Values are presented as mean ± SD

1) Independent t-test

* $P < 0.05$

Table3 . Fasting plasma glucose and postprandial plasma glucose – revision of early stage fasting glucose, compare between two groups during the forth visit

			Test group (n=29)	Placebo group (n=28)	*P*-value[1)]
Blood glucose (mg/dl)	Fasting Plasma Glucose		97.21 ± 8.99	107.99 ± 12.74	<0.001***
	Postprandial plasma glucose	15 min	103.28 ± 11.79	113.26 ± 13.16	0.004**
		30 min	133.93 ± 21.08	150.18 ± 23.21	0.008**
		60 min	139.98 ± 24.99	153.55 ± 34.93	0.096
		90 min	131.21 ± 24.09	143.30 ± 31.45	0.108
		120 min	124.97 ± 21.47	134.03 ± 24.08	0.139
	Total AUC (mg*min/dl)		15301.87 ± 2089.60	16803.93 ± 2718.66	0.023*

Values are presented as mean ± SD

[1)] Independent t-test

* *P* <0.05, ** *P* <0.01, *** *P* <0.001

2. Oral Glucose Tolerance Test(OGTT)

Table 4. Fasting plasma glucose and postprandial plasma glucose – revision of early stage fasting glucose, compare between two groups during the primary visit

			Test group (n=29)	Placebo group (n=28)	*P*-value[1)]
Blood glucose (mg/dl)	Fasting Plasma Glucose	-40 min	100.00 ± 0.00	100.00 ± 0.00	-
		0 min	95.99 ± 5.05	98.80 ± 4.62	0.032*
	Postprandial plasma glucose	15 min	119.01 ± 17.63	125.81 ± 13.68	0.110
		30 min	159.34 ± 24.07	158.94 ± 26.24	0.953
		60 min	173.15 ± 34.81	159.79 ± 35.82	0.159
		90 min	159.23 ± 38.47	153.20 ± 36.75	0.548
		120 min	141.86 ± 38.40	133.24 ± 30.65	0.354
Total AUC (mg*min/dl)			22109.11 ± 2501.39	21568.51 ± 2635.08	0.430

Values are presented as mean ± SD

1) Independent t-test

* $P < 0.05$

Table5 Fasting plasma glucose and postprandial plasma glucose – revision of early stage fasting glucose, compare between two groups during the fifth visit

			Test group (n=29)	Placebo group (n=28)	*P*-value[1)]
Blood glucose (mg/dl)	Fasting Plasma Glucose	−40 min	96.35 ± 6.87	103.91 ± 10.83	0.003**
		0 min	96.16 ± 11.48	107.66 ± 17.44	0.005**
	Postprandial plasma glucose	15 min	123.94 ± 20.74	140.08 ± 21.09	0.005**
		30 min	152.43 ± 25.2	167.11 ± 27.32	0.040*
		60 min	151.75 ± 32.11	167.28 ± 41.10	0.117
		90 min	143.36 ± 37.46	151.61 ± 39.15	0.420
		120 min	128.04 ± 31.51	140.03 ± 36.89	0.192
	Total AUC (mg•min/dl)		20634.00 ± 3082.06	22566.65 ± 3421.58	0.029*

Values are presented as mean ± SD

[1)] Independent t-test

* $P<0.05$, ** $P<0.01$