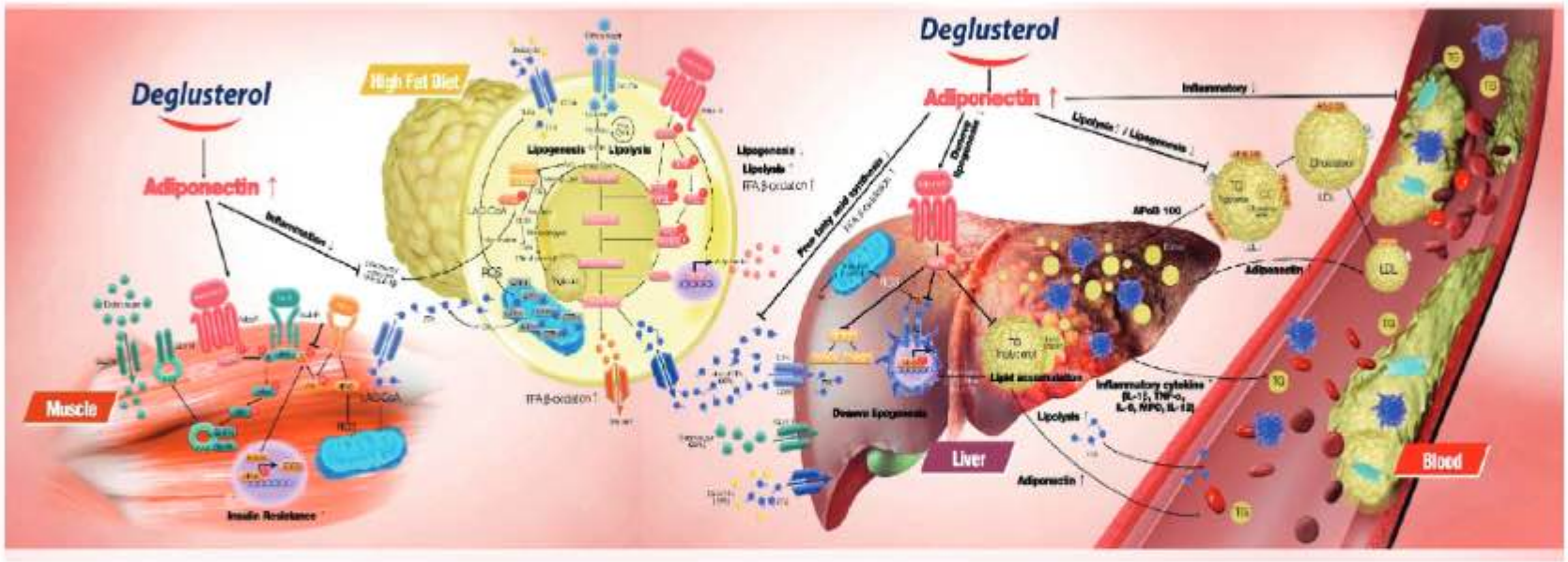
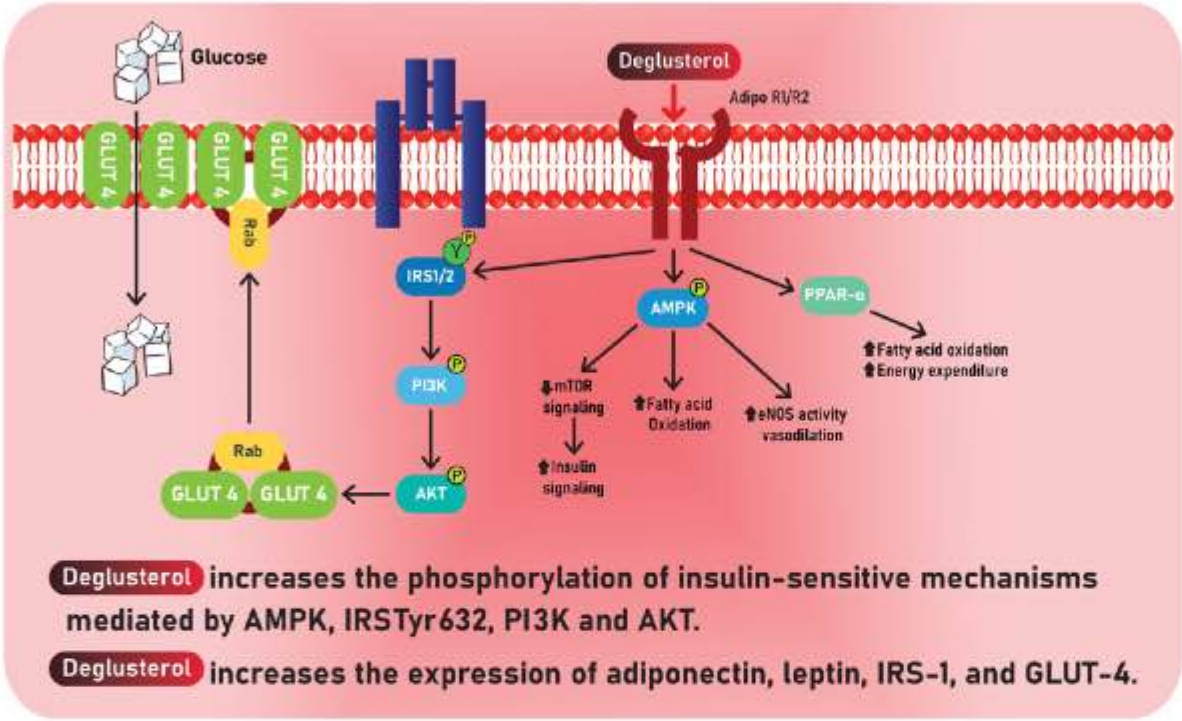
Each sachet contains:

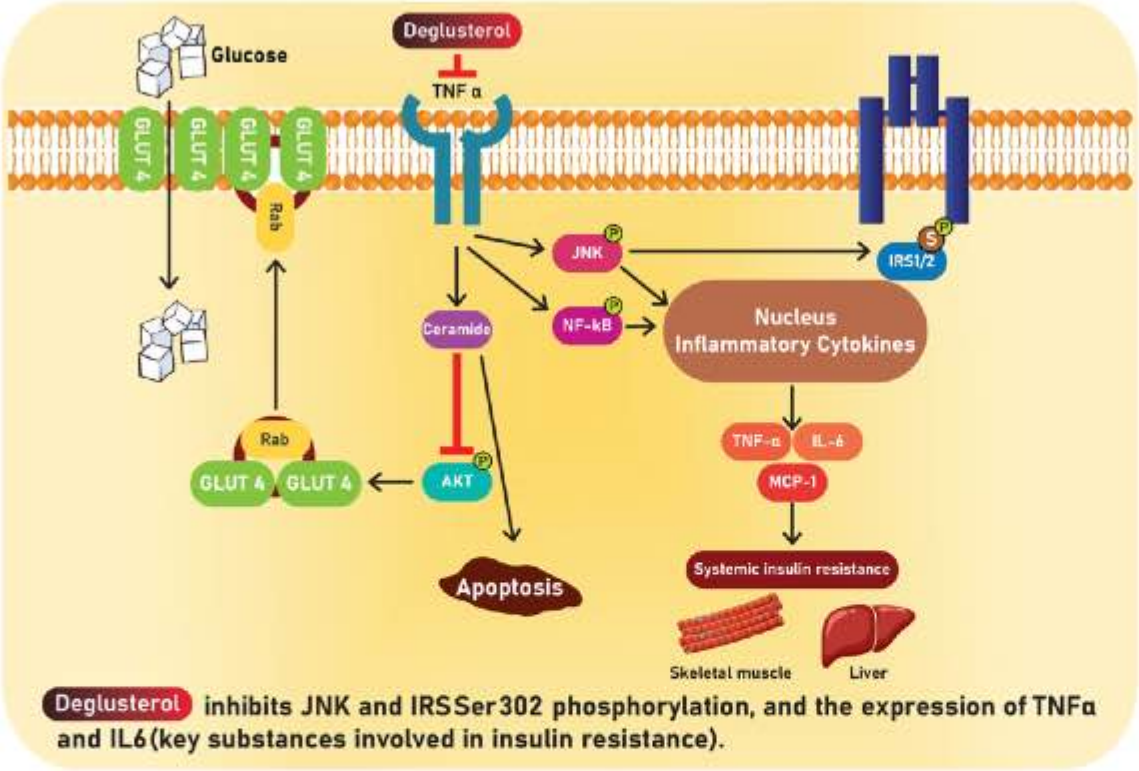
- **30 mg Deglusterol**, consisting of:
- 15 mg **Adiporin (Adiponectin agonist)**
- 15 mg **Deobetide (anti-inflammatory)**


Deglusterol
Adiponectin ↑
Inflammation ↓
High Fat Diet
Lipogenesis ↓
Lipolysis ↑
FFA β-oxidation ↑
Muscle
Insulin Resistance ↑
Deglusterol
Adiponectin ↑
Inflammation ↓
Lipolysis ↑ / Lipogenesis ↓
Free fatty acid synthesis ↓
FFA β-oxidation ↑
Oxidative lipogenesis
ApoB 100
Adiponectin ↑
Liver
Lipid accumulation
Inflammatory cytokine ↑
Lipolysis ↑
Adiponectin ↑
Blood
LDL



Deglusterol increases the phosphorylation of insulin-sensitive mechanisms mediated by AMPK, IRSTyr632, PI3K and AKT.

Deglusterol increases the expression of adiponectin, leptin, IRS-1, and GLUT-4.



Deglusterol inhibits JNK and IRSSer302 phosphorylation, and the expression of TNFα and IL6(key substances involved in insulin resistance).

FDA approval

U.S. FOOD & DRUG ADMINISTRATION

(b) (4)

March 21, 2022

Dear (b) (4)

This letter is to inform you that the Food and Drug Administration (FDA) filed your notification that you submitted to FDA, pursuant to 21 United States Code (U.S.C.) § 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)), on January 7, 2022. Additional information was received on March 9 and 11, 2022. Your notification concerns a new dietary ingredient you describe as a "mixture of (b) (4) " that you intend to market as a bulk dietary ingredient called "Deglusterol powder."

According to your notification, the conditions of use are "30 mg serving size, 1 serving/day, consumed on a chronic daily basis." The target population is "Adults. Dietary supplement products containing Deglusterol powder are not intended for pregnant and lactating women or children."

FDA approval

SECTION B – CHEMISTRY AND IDENTITY

B.6 Intended Use Level of the New Dietary Ingredient

Caregen is the bulk ingredient manufacturer of Deglusterol powder. Te ingredient is intended to be used in dietary supplement products intended for use by adults at levels of up to 30 mg/day to support a healthy blood sugar level.

SECTION C – SAFETY AND TOXICOLOGY

The scientific evidence provided in the Sections below, along with the history of use in dietary supplements, collectively support that the use of Deglusterol powder as an NDI at levels of up to 30 mg/day will reasonably expected to be safe.

https://www.fda.gov/media/160660/download
https://www.regulations.gov/document/FDA-2022-S-0023-0015

In-vitro , In-vivo study

J Med Food. 2022 Feb;25(2):166-176. doi: 10.1089/jmf.2021.K.0159.

Lowering of Blood Glucose Levels with the Peptide Mixture Deglusterol in *In Vitro* and *In Vivo* Models

Eun Mi Kim [1], Seon Soo Kim [1], Yong Ji Chung [1]

Affiliations + expand

PMID: 35148196 DOI: 10.1089/jmf.2021.K.0159

Abstract

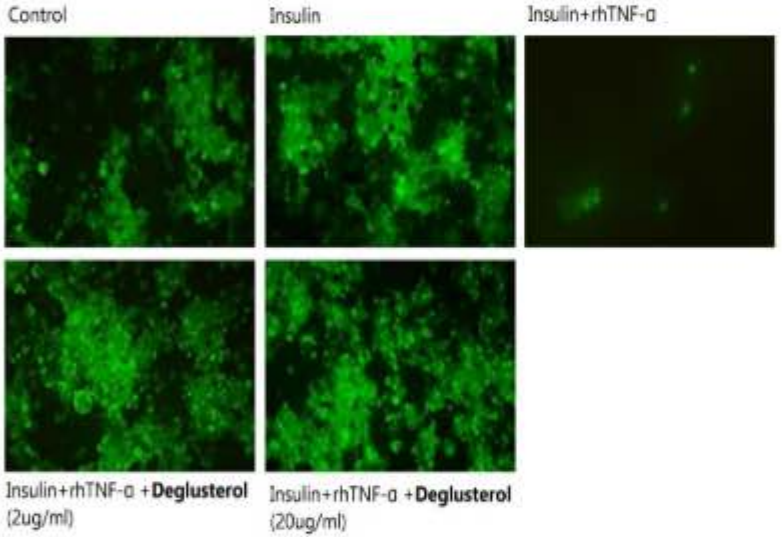
This study aimed to investigate the blood glucose-lowering effect of the peptide complex Deglusterol, which was isolated from corn extract, in insulin-resistance models. It was found to inhibit insulin receptor substrate (IRS) Ser302 phosphorylation, known as the insulin resistance mechanism, through the inhibition of tumor necrosis factor-α (TNF-α) signaling and the induction of AMP-activated protein kinase phosphorylation. Furthermore, the phosphorylation of IRS Tyr632, phosphoinositide 3-kinase (PI3K), and AKT that is involved in the insulin action mechanism was decreased by TNF-α, whereas Deglusterol increased their phosphorylations, leading to an increase of glucose uptake rate by 190% through glucose transporter type 4 (GLUT4) compared with TNF-α-treated group in C2C12 cells. In addition to insulin signaling activation, Deglusterol treatment resulted in significantly greater mRNA expressions of IRS (190%) and GLUT4 (140%) as well as that of leptin (260%) and adiponectin (140%), which are indicators of insulin sensitivity. In animal models with type 2 diabetes, the blood glucose concentrations in the Deglusterol-administered group were significantly reduced by 50% compared with the control group. Deglusterol suppressed insulin resistance and restored insulin sensitivity, which contributed to lowering blood glucose concentrations in the insulin-resistant models, suggesting its potential as a blood glucose-lowering agent for people at high risk of type 2 diabetes or prediabetes.

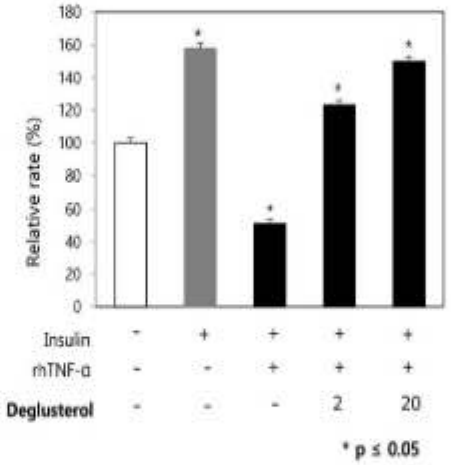
In-vitro , In-vivo study

1. Effect of Deglusterol on Glucose uptake

1) Glucose uptake in pre-adipocyte

Cell: 3T3-L1 (Preadipocyte)





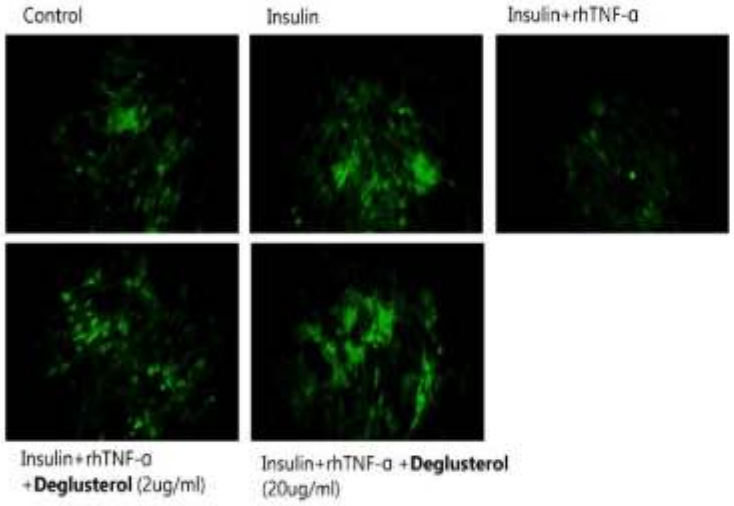
2-NBDG uptake was increased in differentiated adipocytes by Deglusterol treatment

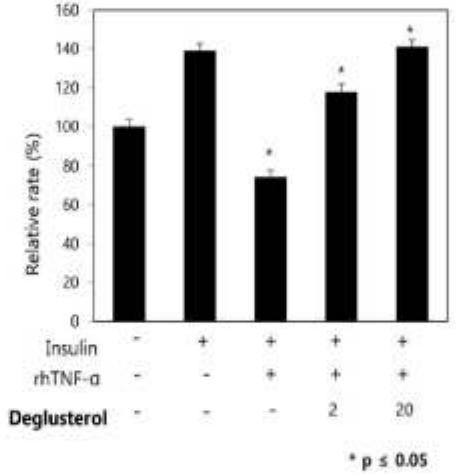
In-vitro . In-vivo study

1. Effect of Deglusterol on Glucose uptake

2) Glucose uptake in Myoblast

Cell: C2C12 (Myoblast)





2-NBDG uptake was increased in differentiated myoblast by Deglusterol treatment

In-vitro , In-vivo study

Deglusterol increased their phosphorylations, leading to an increase of glucose uptake rate by 190% through glucose transporter type 4 (GLUT4) compared with TNF-α-treated group in C2C12 cells. In addition to insulin signaling activation, Deglusterol treatment resulted in significantly greater mRNA expressions of IRS (190%) and GLUT4 (140%) as well as that of leptin (260%) and adiponectin (140%), which are indicators of insulin sensitivity

Clinical study in 2019, South Korea

Human Study Report

A 12 weeks, multi-center, randomized, double-blind, parallel, placebo-controlled human study to evaluate the efficacy and safety of Deglusterol (CG-DL) on fasting glucose level

Health Functional Foods for Human Study:	Investigational food: Deglusterol Control food: Placebo
Subject for Human Study:	Adults with impaired glucose tolerance, fasting glucose, or belonging to a high-risk group for diabetes
Human Study Protocol Number:	CG-DL01
Human Study Start Date:	November 12, 2018
Human Study End Date:	June 7, 2019

Sponsor of Human Study:	Caregen Co., Ltd. Address: 46-38, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea 031-420-9200
Person in Charge of the Human Study:	Hallym University Sacred Heart Hospital Family Medicine Professor Yu-Jin Paek
Results Report Version/Date	V 1.0 / 30-AUG-2019

HOMA-IR

There was statistically significant difference in the HOMA-IR (insulin resistance) changes between the two groups at visit in week 12 compared to baseline. it was confirmed that in week 12, those of the test group (Deglusterol) decreased to -0.44±0.94, while those of the control group increased to 0.44±1.11, thus showing statistically significant difference between the two groups (P-value = 0.001) In other words, it was confirmed that the intake of Deglusterol (CG-DL) reduced the HOMA-IR at 12 weeks compared to the baseline, and HOMA-IR also decreased with the same trend as insulin decreased.

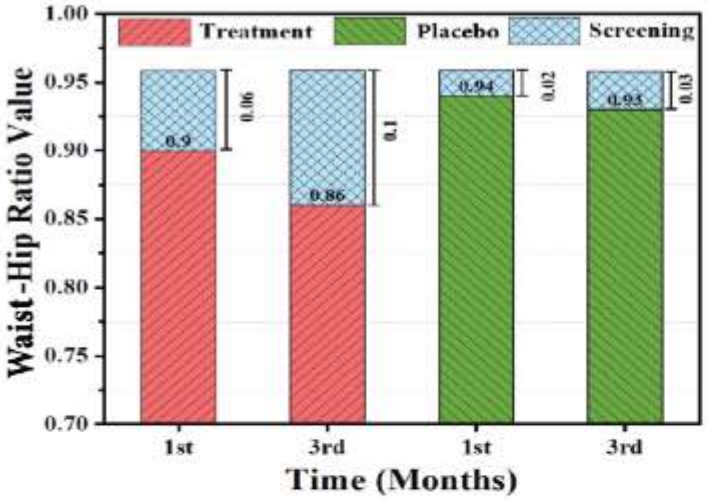
Clinical Study in 2025, Iran

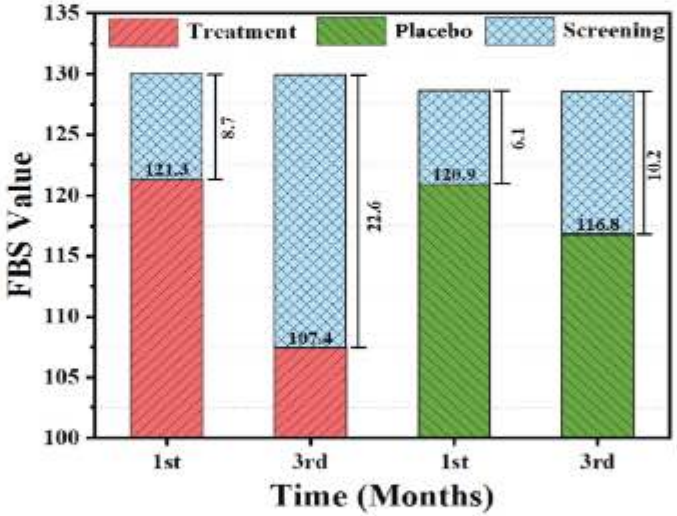
Title:

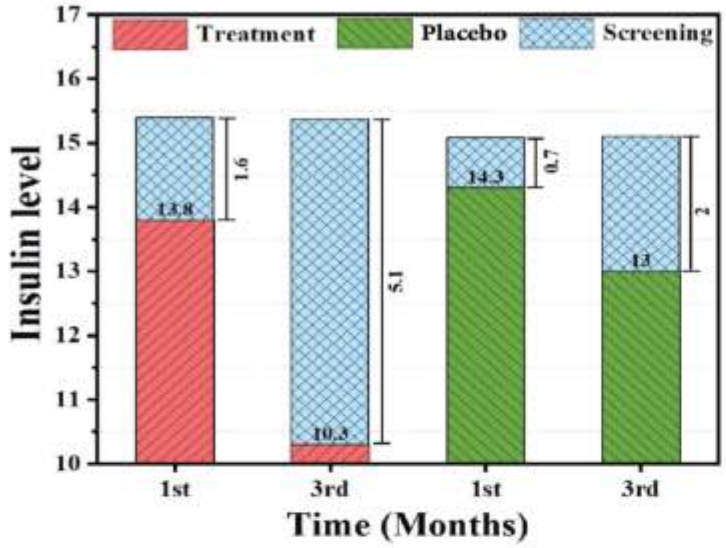
A randomized, double blind, placebo-controlled clinical trial for evaluation of the efficacy and safety of ProGsterol (Deglusterol) versus placebo in patients with Metabolic syndrome and NAFLD (Non Alcoholic Fatty Liver Disease)

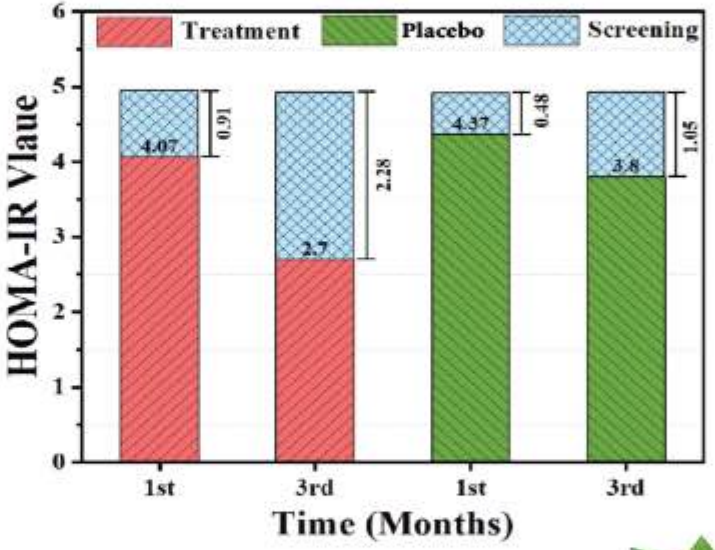
Edit: 0-1

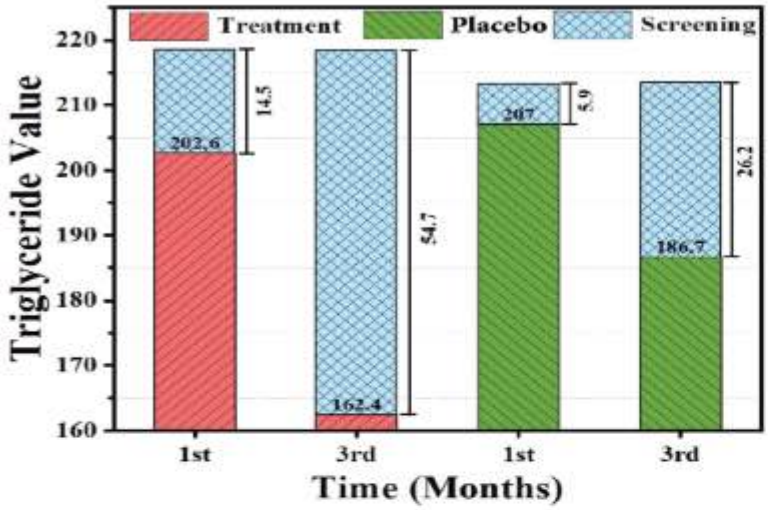
Date: March 2025

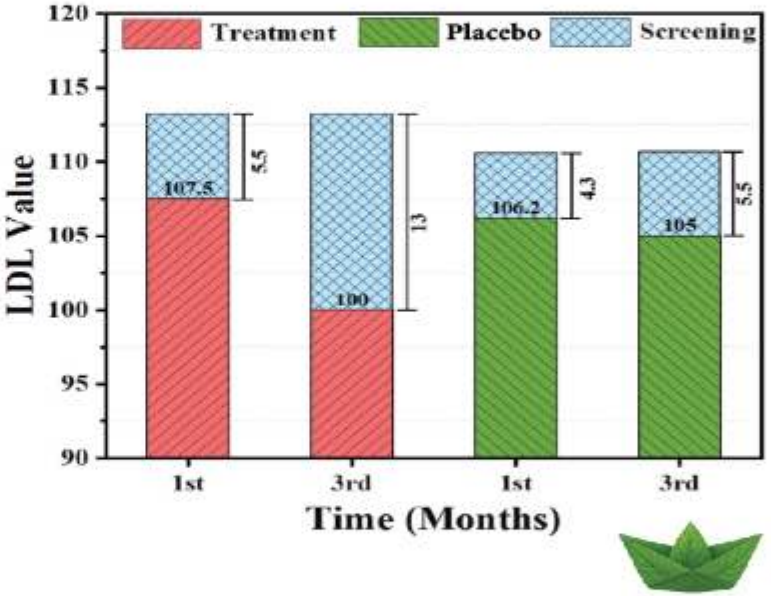

Treatment
Placebo
Screening
Waist-Hip Ratio Value
1.00
0.95
0.90
0.85
0.80
0.75
0.70
0.9
0.86
0.94
0.93
0.06
0.1
0.02
0.03
1st
3rd
1st
3rd
Time (Months)

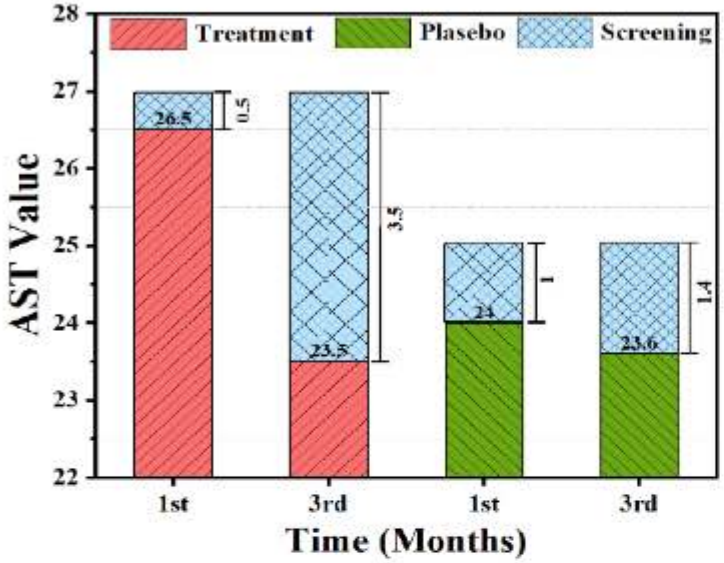

Treatment
Placebo
Screening
FBS Value
135
130
125
120
115
110
105
100
121.3
107.4
120.9
116.8
8.7
22.6
6.1
10.2
1st
3rd
1st
3rd
Time (Months)

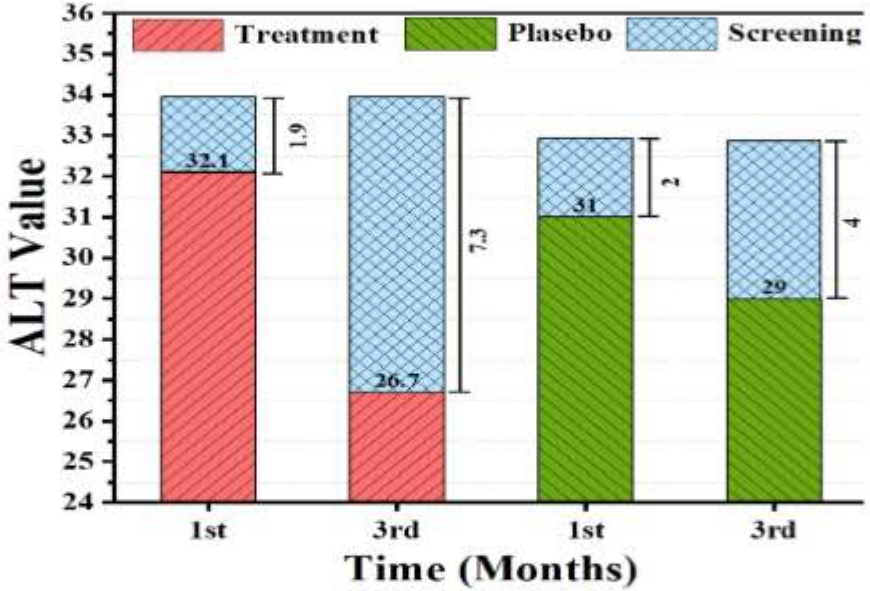

Treatment
Placebo
Screening
Insulin level
17
16
15
14
13
12
11
10
13.8
1.6
10.3
5.1
14.3
0.7
13
2
1st
3rd
1st
3rd
Time (Months)


Treatment
Placebo
Screening
HOMA-IR Vlaue
6
5
4
3
2
1
0
4.07
0.91
2.7
2.28
4.37
0.48
3.8
1.05
1st
3rd
1st
3rd
Time (Months)


Treatment
Placebo
Screening
Triglyceride Value
220
210
200
190
180
170
160
202.6
14.5
162.4
54.7
207
5.9
186.7
26.2
1st
3rd
1st
3rd
Time (Months)


Treatment
Placebo
Screening
LDL Value
120
115
110
105
100
95
90
107.5
5.5
100
13
106.2
4.3
105
5.5
1st
3rd
1st
3rd
Time (Months)


Treatment
Plasebo
Screening
AST Value
Time (Months)
1st
3rd
1st
3rd
26.5
23.5
23
23.6
0.5
3.5
1
1.4


Treatment
Plasebo
Screening
ALT Value
Time (Months)
1st
3rd
1st
3rd
32.1
26.7
31
29
1.9
7.3
2
4

A randomized, double blind, placebo-controlled clinical trial for evaluation of the efficacy and safety of ProGsterol (Deglusterol) plus antidiabetic agents versus antidiabetic agents plus placebo in patients with type 1 or 2 diabetes mellitus

A

- T2DM
- HbA1c: 6.5 - 8%
- Metformin plus PROGSTEROL, Metformin plus Placebo

B

- T2DM
- HbA1c: 6.5 - 8%
- Sitagliptin and Metformin plus PROGSTEROL, Sitagliptin and Metformin plus Placebo

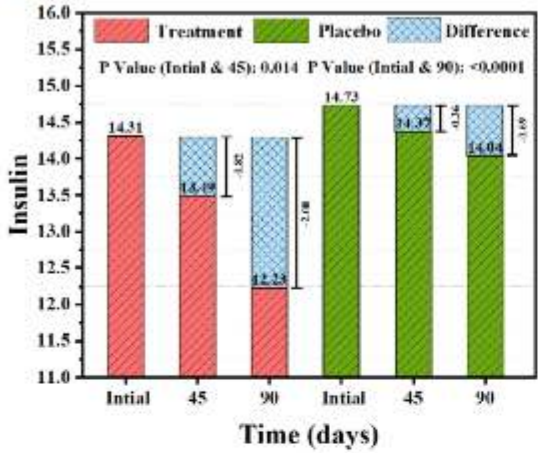
C

- T2DM
- HbA1c: 6.5 - 8%
- Empagliflozin and Metformin plus PROGSTEROL, Empagliflozin and Metformin plus Placebo

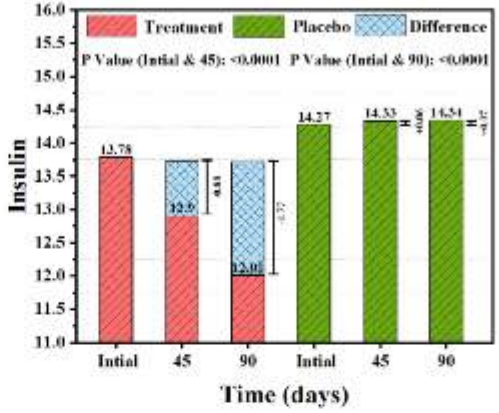
D

- T1DM
- HbA1c: 7 - 8%
- Insulin plus PROGSTEROL , Insulin plus Placebo

A



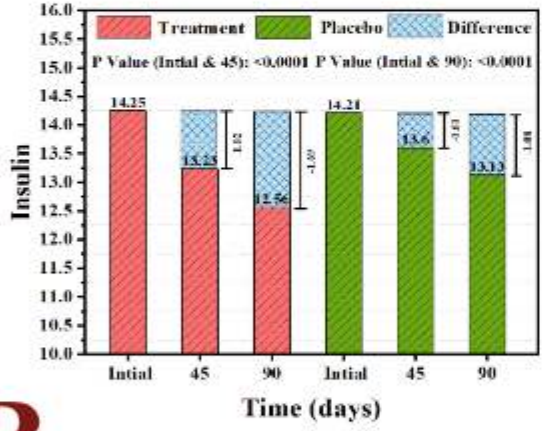
C



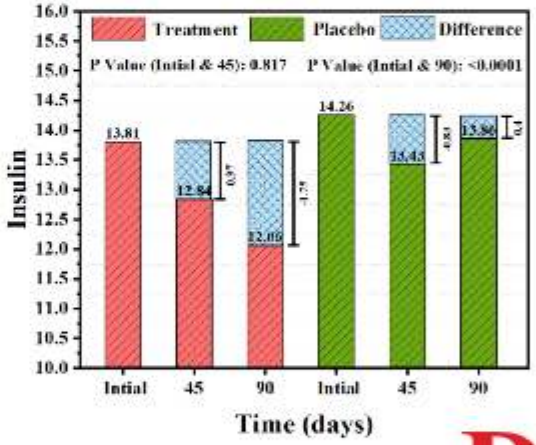
proGsterol

Insulin

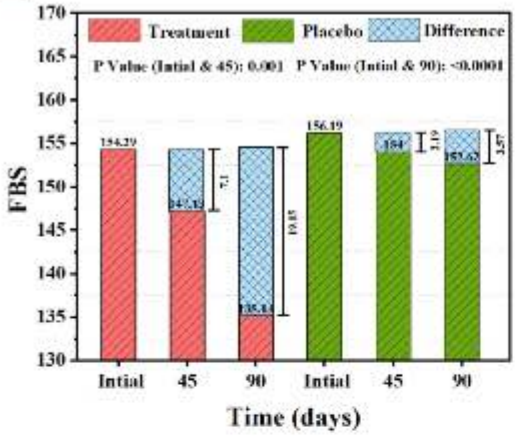
B



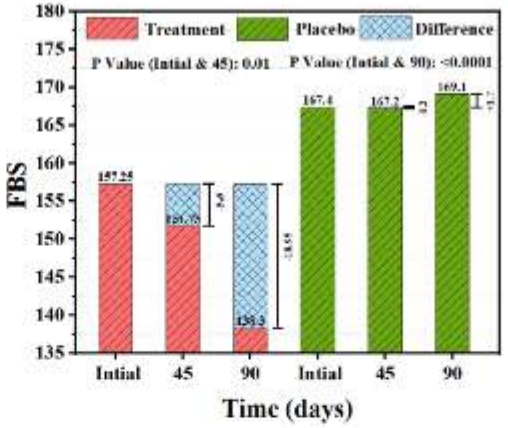
D



A

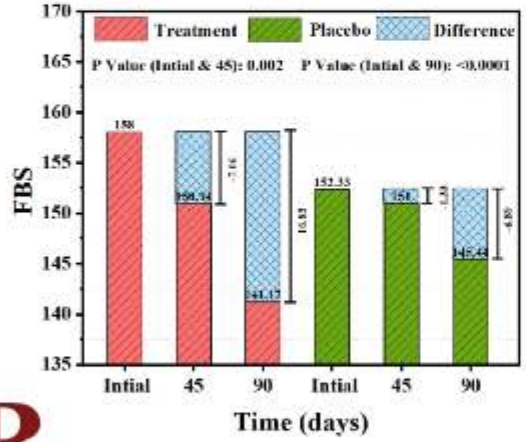


C

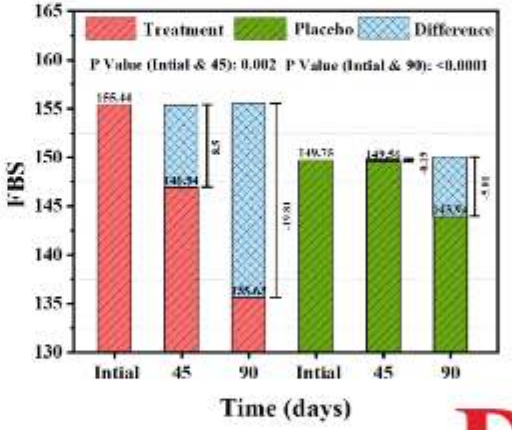


proGsterol

FBS

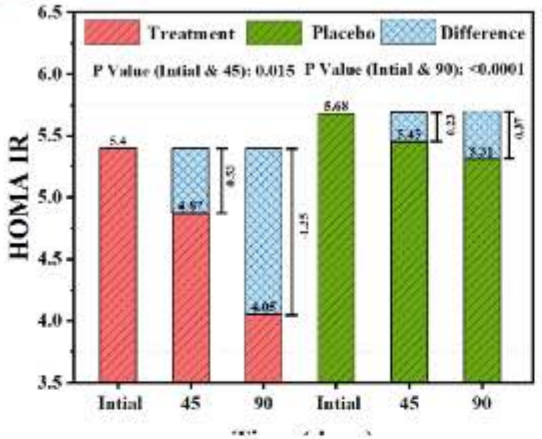


B

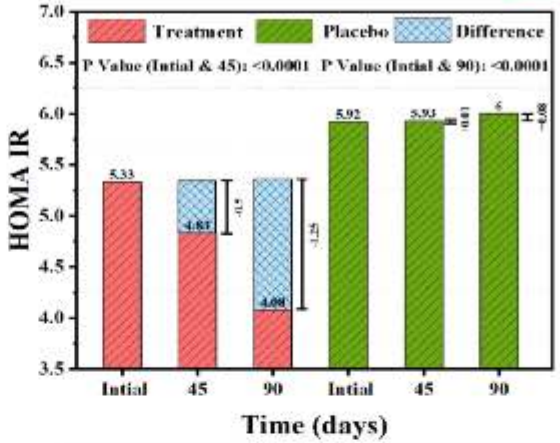


D

A

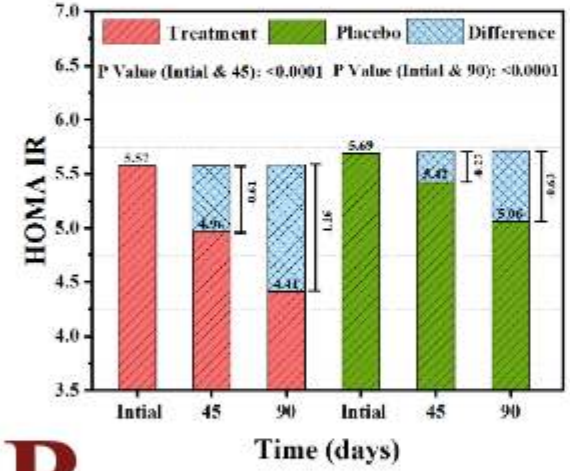


C

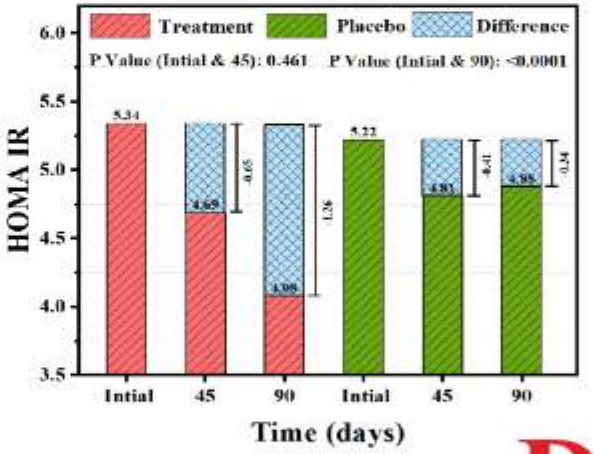


proGsterol

HOMA-IR



B



D

Outcome	Finding
HbA1c Reduction	Decrease of 0.3–0.4% across treatment groups
Fasting Blood Sugar (FBS)	Average reduction of 18-20 units
Weight Change	Weight loss of 3–4 kg across relevant groups
Insulin Resistance	
Fasting Insulin Levels	Reduction of 1.6–2 μIU/mL, indicating improved insulin sensitivity
HOMA-IR Index	Decrease consistent with reduced fasting insulin, supporting ProGsterol's effect on metabolic syndrome and insulin resistance

A randomized, double blind, placebo-controlled clinical trial for evaluation of the efficacy and safety of ProGsterol (Deglusterol) versus placebo in patients with Poly Cystic Ovary Syndrome (PCOS) Candidate for ART

A randomized, double blind, placebo-controlled clinical trial for evaluation of the efficacy and safety of ProGsterol (Deglusterol) versus placebo in patients with Non Alchoholic Steatohepatitis (NASH)

Our Health Challenge :

Sara

ProGsterol 30 days every other day, Calories reduction

Aerobic exercise done 2 times a week,

Significant reduced appetite to snaks and sugary foods

5 kg visceral fat reduction, 1.5 kg muscle gaining

Zahra

ProGsterol 14 sachets ProGsterol, 7 sachet every other day first 2 weeks, 7 sachets everyday last days befor body analysis

Exercise 30 minutes each day

Calorie reduction due to lesser sugar craving

(I used to love Dates and chocolates during though hours).

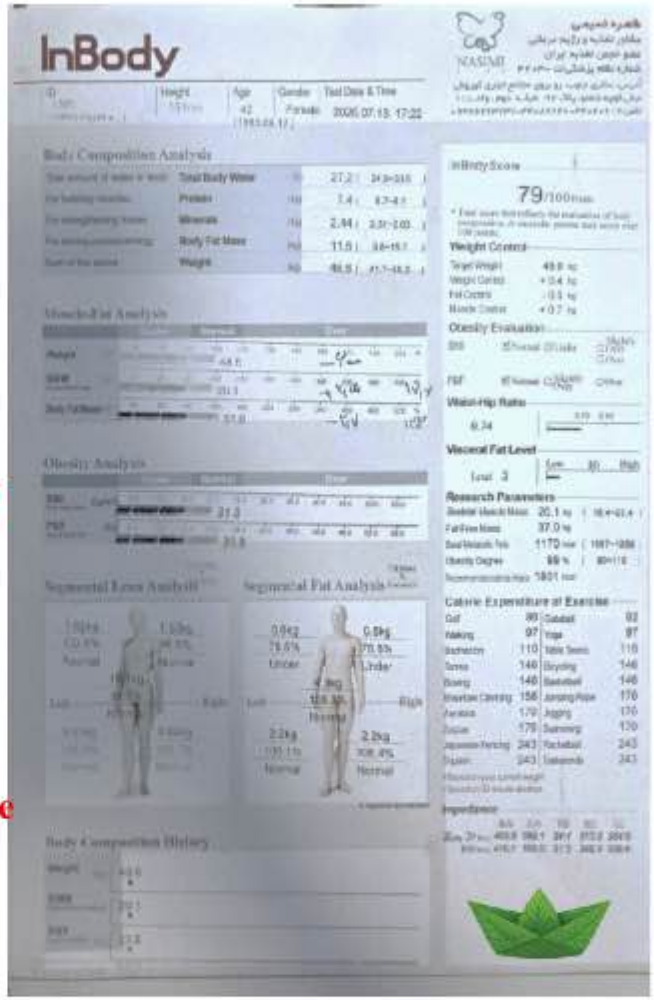
Hamed

ProGsterol 2 months every day, No diet change, No exercise

Lowering junk food craving

1.7 kg visceral fat reduction

1 kg muscle gaining



How to use:

Take 1 sachet with water (100 cc water) once a day (before breakfast)

proGsterol

Next-generation therapy for metabolic balance

کد نسخه الکترونیک:

۴۳۴۷۱

۴۰۹۶۰

proGsterol

پروجی استرول

تحت پوشش بیمه های تکمیلی:

بیمه معلم

بیمه سپه

بیمه سینا

بیمه ملت

بیمه سامان

بیمه SOS

بیمه فولاد مبارکه

بیمه صادرات

بیمه آسیا