

# The effect of Korean red ginseng on glucose metabolism and diabetic complications in type 2 diabetes mellitus

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<b>Registration date</b> 05/09/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/10/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English Summary

### Background and study aims

Red ginseng is a herbal medicine that has been used for a long time. It is known to have various effects on the central nervous system, cardiovascular system, endocrine system and immune system. Among them, various studies have revealed that red ginseng has an effect on blood vessels and thus has a good effect on arteriosclerosis (the thickening and hardening of the walls of the arteries) and lowering blood glucose. The aim of this study is to investigate the effects of red ginseng on oxidative stress and end glycation products, which are known to play a major role in diabetic complications.

### Who can participate?

Patients between 19 and 75 years of age with type 2 diabetes

### What does the study involve?

Participants are randomly allocated to receive either Korean red ginseng capsules or placebo (dummy) capsules. They are instructed to take two tablets twice a day for 24 weeks. No other medication is prescribed and the participants' original diabetes medication is not changed. Blood glucose levels and markers of diabetic complications are measured after 24 weeks.

### What are the possible benefits and risks of participating?

During the study period, red ginseng tablets and tests for glucose metabolism and diabetes complications are provided free of charge. The risk is low because red ginseng is already approved as a health functional food and a commercially available medicine.

### Where is the study run from?

Gangnam Severance Hospital (South Korea)

### When is the study starting and how long is it expected to run for?

March 2016 to August 2017

Who is funding the study?  
Korea Ginseng Corporation (South Korea)

Who is the main contact?

1. Dr Jisun Nam
2. Dr Chul Woo Ahn

## Contact information

### Type(s)

Scientific

### Contact name

Dr Jisun Nam

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### Type(s)

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Dr Chul Woo Ahn

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

3-2015-0331

## Study information

Scientific Title

Effect of oral administration of red ginseng on glucose metabolism and diabetic complications in type 2 diabetic patients

### **Study hypothesis**

Taking red ginseng in patients with type 2 diabetes will improve glucose metabolism and diabetic complications.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Gangnam Severance Hospital, 12/16/2015, ref: IRB 3-2015-0331

### **Study design**

Single-center interventional double-blind randomized placebo-controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

No participant information sheet available

### **Condition**

Diabetes mellitus

### **Interventions**

Enrolled subjects were randomized using a computer generated randomization table. Subjects were randomized to receive Korean red ginseng capsules or placebos for 24 weeks. They were instructed to take two tablets of Korean red ginseng or placebo twice a day (taking total 2 grams a day). No other medication was prescribed and the patients' original diabetes medication remained unchanged.

### **Intervention Type**

Supplement

### **Primary outcome measure**

Diabetic microvascular complication markers (estimated glomerular filtration rate (eGFR), urinary albumin to creatinine ratio (uACR), Kidney injury molecule-1 (KIM1), laminin-P1 as a marker for diabetic retinopathy, and current perception thresholds (CPT)), measured at week 24

### **Secondary outcome measures**

Fasting plasma glucose and HbA1c, measured by blood test at week 24

**Overall study start date**

02/03/2016

**Overall study end date**

02/08/2017

## Eligibility

**Participant inclusion criteria**

1. Men and women between 19 and 75 years of age with Type 2 diabetes on oral antidiabetic agents
2. Diagnosed with Type 2 diabetes more than 6 months ago
3. Unchanged dose or type of antidiabetic agents within the last 3 months

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

83

**Participant exclusion criteria**

1. Patients with HbA1c > 10%
2. Patients with eGFR < 30 mL/min/1.73 m<sup>2</sup>, AST/ALT > 3 times greater the upper normal limit
3. Taking glucocorticoid or any herbal medicine within the past 3 months
4. Chronic inflammatory disease in the active phase or acute infection status
5. Pregnant or lactating women

**Recruitment start date**

07/03/2016

**Recruitment end date**

07/01/2017

## Locations

**Countries of recruitment**

Korea, South

**Study participating centre**

**Gangnam Severance Hospital**  
Korea, South  
06273

## Sponsor information

### Organisation

Korea Ginseng Corporation

### Sponsor details

71, Beotkkot-gil  
Daedeok-gu  
Daejeon  
Korea, South  
34337

### Sponsor type

Industry

### Website

<https://www.kgc.co.kr>

## Funder(s)

### Funder type

Industry

### Funder Name

Korea Ginseng Corporation

## Results and Publications

### Publication and dissemination plan

Planned publication in July 2018.

### Intention to publish date

01/07/2018

### Individual participant data (IPD) sharing plan

All data collected for clinical research will be stored on a computer with limited access to which the subject identification information is coded, the stored data will be kept secure and a safety check will be made by the researcher.

## IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		11/12/2018	11/12/2018	No	No
<a href="#">Results article</a>		18/01/2020	11/10/2023	Yes	No