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

Submission date
26/07/2017

Recruitment status
No longer recruiting

Registration date
05/09/2017

Overall study status
Completed

Last Edited
11/10/2023

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

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

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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 objectives
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

Health condition(s) or problem(s) studied
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

Completion date
02/08/2017

Eligibility

Key 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

Key exclusion criteria
1. Patients with HbA1c>10%
2. Patients with eGFR < 30 mL/min/1.73 m2, 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

Date of first enrolment
07/03/2016

Date of final enrolment
07/01/2017

Locations

Countries of recruitment
Korea, South

Study participating centre

Gangnam Severance Hospital
Korea, South
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Sponsor information

Organisation
Korea Ginseng Corporation

Sponsor details
71, Beotkkot-gil
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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?
Basic results		11/12/2018	11/12/2018	No	No
Results article		18/01/2020	11/10/2023	Yes	No