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The efficacy and safety study of PURIAM110 on pre-diabetes, diabetes mellitus not insulin requiring stage Korean adults

Submission date
27/08/2010

Recruitment status
No longer recruiting

Registration date
27/09/2010

Overall study status
Completed

Last Edited
18/12/2020

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
P110

Study information

Scientific Title

The efficacy and safety study of PURIAM110 (dietary supplement) on pre-diabetes, diabetes mellitus not insulin requiring stage Korean adults: a randomised double-blind, placebo-controlled, multicentre clinical trial

Acronym
PURIAM110

Study objectives
PURIAM110, a dietary supplement, might be useful for controlling blood glucose concentration in pre-diabetes, diabetes mellitus not insulin requiring stage Korean adults.

As of 14/12/2010 this record was updated to include an extended anticipated end date of 30/04/2011. The previous anticipated end date was 30/04/2007.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board of the Kyung Hee Oriental Medical Center approved on the 21st November 2006 (ref: KOMC IRB 2006-14)
2. Institutional Review Board of the Kyung-won Gil Oriental approved on the 25th October 2006 (ref: 06-101)

Study design
Multicentre randomised double blind placebo controlled clinical trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pre-diabetes, diabetes mellitus not insulin requiring stage.

Interventions
1. Treatment group: PURIAM110 (1:1 mixture of bitter oranges [Fructus Aurantii] and mulberry leaves [Folium Mori]).
2. Control group: placebo.

Both treatment and placebo group dosage is 2.760 mg (total 6 capsules) daily (460 ± 10 mg/1 capsule, 3 capsules/time, 2 times/day - 3 capsules before breakfast and 3 capsules before dinner), total 6 weeks.

Intervention Type
Other

Phase
Phase II/III

Primary outcome(s)

1. Glycated haemoglobin (HbA1c)
2. Fructosamine
3. Fasting glucose
4. 2-hour Oral Glucose Tolerance Test (OGTT)
5. Fasting insulin
6. Total cholesterol
7. Triglyceride
8. Low density lipoprotein (LDL) cholesterol

Assessing the difference between baseline and 6 week measurements.

Key secondary outcome(s))
1. Visual Analogue Scale (VAS):
1.1. Polydipsia
1.2. Polyuria
2. Other clinically significant parameters
3. Anthropometric parameters:
3.1. Body weight
3.2. Waist circumference
3.3. Hip circumference

Completion date
30/04/2011

Eligibility

Key inclusion criteria
1. Either sex between the ages of 18 - 69 years, eligible for the trial through screening test prior to the enrollment
2. Able and willing to perform the study protocol and participate throughout the entire trial period (screening, baseline, 3, 6 weeks, 8 week-follow up [if needed])
3. Participants who understood the study thoroughly and signed a written informed consent
4. Among individuals not under diabetes mellitus treatment, whose random glucose concentration is 110~250 mg/dL measured with Accu-Chek® glucometer within 3 weeks prior to participation
4.1. Fasting plasma glucose concentration 100-190mg/dl or
4.2. 2-hour plasma glucose concentration* 130-250 mg/dl
(*venous plasma glucose 2-hour after ingestion of 75g oral glucose load)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Presently using other blood glucose level controlling agents
2. History of allergy to the herbal products(bitter orange and Mulberry leaves) or allergic diseases such as asthma
3. Medication (within the last 1 month or during the study) which would affect the study results
4. Daily intake of alcoholic beverages
5. Smokers consuming more than 1 pack/day
6. Presently having acute diseases or other untreated illness requiring treatment
7. Impaired hepatic or renal functions
8. Pregnant, breast feeding status or female of reproductive age, not using proper contraception
9. Participant in other clinical trials or a blood donor, within the past 1 month
10. History of severe disease or any condition, in the investigators opinion, that would endanger the individuals safety or affect the study result
11. Patients with type I and type II diabetes mellitus (insulin requiring stage)

Date of first enrolment
01/12/2006

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
Korea, South

Study participating centre
Department of Preventive Medicine
Seoul
Korea, South
130-701

Sponsor information

Organisation
Korea Health Industry Development Institute (KHIDI) (South Korea)

ROR
https://ror.org/00fdzyk40

Funder(s)

Funder type
Government

Funder Name
Ministry for Health, Welfare & Family Affairs (South Korea) - Korea Healthcare technology R&D Project (ref: A060793)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/02/2011		Yes	No