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Pycnogenol® to reduce use of commercial anti-hypertensive medications: a randomised, double-blind, placebo-controlled, prospective, 15-week study

Submission date
18/10/2007

Recruitment status
No longer recruiting

Registration date
31/10/2007

Overall study status
Completed

Last Edited
31/10/2007

Condition category
Circulatory System

[_] Prospectively registered
[_] 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

Contact name
Prof Ronald Watson

Contact details
Mel and Enid Zuckerman College of Public Health
University of Arizona, Health Science Center
1295 N. Martin
P. O. Box 245155 [FedEx building 202 room 252]
Tucson
United States of America
85724-5155

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Pycnogenol®, a natural product, a "complementary or alternative medicine", will reduce the use of antihypertensive medicines (Angiotensin Converting Enzyme [ACE] inhibitors) and Cardiovascular Disease (CVD) risk factors in subjects with both hypertension and type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Human Subjects Protection Program at University of Arizona on the 16th August 2003 (ref: 03-129).

Study design
Single-centre, interventional, randomised double-blind placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular risk factors in diabetes

Interventions
Oral administration of Pycnogenol® pills (25 mg, 5 times a day) or matched inactive placebo for 12 weeks. Total duration of follow-up is 15 weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pycnogenol®

Primary outcome measure
Measured at 12th week of treatment:
1. Blood pressure, measured on the left arm after 10 minutes rest (Korotkoff sounds I and V were taken as the systolic and diastolic blood pressures)
2. Serum endothelin-1
3. Fasting Low Density Lipoprotein (LDL)-cholesterol
4. Glycosylated haemoglobin (HbA1c)
5. Fasting plasma glucose
6. Urinary albumin concentration

Secondary outcome measures
Measured at 4th and 8th week of treatment:
1. Blood pressure, measured on the left arm after 10 minutes rest (Korotkoff sounds I and V were taken as the systolic and diastolic blood pressures)
2. Serum endothelin-1
3. Fasting Low Density Lipoprotein (LDL)-cholesterol
4. Glycosylated haemoglobin (HbA1c)
5. Fasting plasma glucose
6. Urinary albumin concentration

Overall study start date
01/08/2003

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. Men and women, 40 - 75 years of age
2. Non-insulin dependent type 2 diabetes
3. Receiving pharmaceutical treatment (ACE-inhibitors) for hypertension
4. Pre-trial systolic blood pressure of 130 - 150 mmHg

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria

1. Type 1 diabetes
2. Use of insulin
3. Any supplements other than single daily multivitamin
4. Having any major illness such as cancer, asthma, or heart failure
5. Any previous cardiac events
6. Pregnancy, or being nursing mother

Date of first enrolment
01/08/2003

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
United States of America

Study participating centre
Mel and Enid Zuckerman College of Public Health
Tucson
United States of America
85724-5155

Sponsor information

Organisation
Horphag Research Ltd (Switzerland)

Sponsor details
P.O. Box 80
Avenue Louis-Casai 71
Cointrin
Geneva
Switzerland
CH-1216

Sponsor type
Industry

Website
http://www.horphag.com

ROR
https://ror.org/003n34405

Funder(s)

Funder type
Industry

Funder Name
Horphag Research Ltd (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration