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Salacia extract improves post-prandial glucose and insulin response

Submission date	Recruitment status	[_] Prospectively registered
17/02/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/02/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/07/2018	Other	

Plain English summary of protocol

Background and study aims
The amount of sugar (glucose) in the blood is controlled by a hormone called insulin. If you have diabetes, either the body does not produce enough insulin or the insulin produced doesn't work properly, leading to high blood glucose levels. Extracts of the Salacia species of herb from roots, stems, and leaves are used for the treatment of diabetes in Asia. The aim of this study is to examine the effect of different doses of a new form of Salacia extract (Salacia Chinensis, SCE) on the glucose and insulin response to oral sucrose (sugar) solution in healthy individuals (South Asian Population).

Who can participate?
People aged 18-55, with body mass index (BMI) 24.5 to 29.5 kg/m2

What does the study involve?
Participants are given sucrose solution and Salacia extract, and blood samples are collected at the start and after 30, 60, 90, 120 and 180 minutes to assess their blood glucose and insulin response. Different doses of Salacia extract are tested with a 7-day break in between treatments and results are compared with a placebo (dummy) treatment.

What are the possible benefits and risks of participating?
We will find out whether Salacia supplementation helps to maintain or lower blood glucose and insulin levels after sucrose solution administration. This will help them to understand how to manage blood glucose levels and helps in diabetes condition. Pain associated due to multiple times of blood collection to assess blood glucose and insulin levels.

Where is the study run from?
Semler Research Center (India)

When is the study starting and how long is it expected to run for?
July to December 2015

Who is funding the study?
Atlantic Canada Opportunities Agency

Who is the main contact?
Dr Vijaya Juturu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
OAHT_SE2015

Study information

Scientific Title
Salacia extract improves post-prandial glucose and insulin response: a randomized double-blind placebo-controlled, cross-over study in healthy volunteers

Study objectives
Studies indicate that Salacia extracts modulate multiple targets that influence carbohydrate and lipid metabolism. This study is to examine the effect of differing doses of a novel form of Salacia extract (Salacia Chinensis, SCE) on glucose and insulin response to an oral sucrose load in healthy individuals (South Asian Population).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sri Venkateswara Hospital Ethics Committee , India, 08/06/2015, ref: S-15-1203

Primary study design
Interventional

Study design
Randomized double-blind placebo-controlled cross-over study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Not Applicable

Interventions
Participants will be randomly assigned to ingest Salacia extract at dosages of 200 mg SCE , 300 mg SCE and 500 mg SCE (OmniLeanTM) or placebo (PLA) in a single-center, double-blind, randomized, placebo-controlled four-way cross-over design. Washout period between treatment periods was 7 days. Plasma glucose and plasma insulin responses after 0, 30, 60, 90, 120, 180 min of ingesting oral sucrose standard solution and area under curve for glucose (AUCglucose) and insulin response (AUCinsulin) will be calculated. ANOVA and paired t-tests will be used to examine differences between treatments and over baseline.

Intervention Type
Supplement

Primary outcome(s)
Glucose and insulin responses after 0, 30, 60, 90, 120 and 180 min

Key secondary outcome(s)
AUC glucose and AUC insulin

Completion date
30/12/2015

Eligibility

Key inclusion criteria
1. Male and female subjects aged 18-55 years of age (both ages inclusive), of BMI 24.5 to 29.5 Kg/ m2
2. Participants required to avoid all dietary supplements, OTC or any foods interfere with post-prandial glucose and insulin before and throughout the study period and not allowed to drink alcoholic beverages or caffeine during the period of the study
3. Non smokers
4. No pregnant and lactating women
5. Signed consent form

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Key exclusion criteria
1. Participation in any bioavailability/bioequivalence/pharmacokinetic study or received an investigational drug within a period of 3 calendar months prior to check in of period one
2. Use of dietary supplements to reduce body weight or metabolic health management at least 30 days before check in of period one
3. Use of hormone replacement therapy for a period of 6 calendar months prior to check in of period one
4. History of drug abuse, or alcohol dependence or abuse
5. History of any allergies (asthma, urticaria) including drug allergies
6. Known hypersensitivity or allergy to Salacia extract or any of the excipients or related drugs.
7. Smokers, prescriptions, chronic conditions such as hypertension, diabetes , inflammatory disorders, cardiovascular disease and cancer etc

Date of first enrolment
02/08/2015

Date of final enrolment
08/09/2015

Locations

Countries of recruitment
India

Study participating centre
Semler Research Center
Semler Research Center Pvt. Ltd
P A Arcade, No 21, 22, 23
Kodigehalli Main Road
Sahakarnagar
Bangalore
India
560092

Sponsor information

Organisation
OmniActive Health Technologies Ltd (Canada)

ROR
https://ror.org/05rga6m50

Funder(s)

Funder type
Government

Funder Name
Atlantic Canada Opportunities Agency

Alternative Name(s)
Agence de Promotion Économique du Canada Atlantique, ACOA Canada, Atlantic Canada Opportunities Agency | Moncton NB, ACOA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016		Yes	No