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Can Clovinol (clove extract) lower blood sugar levels after meals in healthy volunteers?

Submission date
21/09/2018

Recruitment status
No longer recruiting

Registration date
28/09/2018

Overall study status
Completed

Last Edited
09/05/2019

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
The main energy source the body uses is sugar (i.e. glucose), which is derived from the food we eat. The amount of sugar in our blood (i.e. blood glucose levels) is an important indicator of overall health. Both too much sugar (hyperglycemia) and too little sugar (hypoglycemia) in the blood is linked with negative effects on health. Fasting blood sugar is measured when someone has not eaten or drunk anything (except water) for at least 8 hours. Normal fasting blood sugar levels should be below 100 mg/dL. Prediabetes is characterized by fasting blood sugar levels between 100 to 125 mg/dL, and diabetes is when fasting blood sugar is greater than 125 mg/dL. When we eat, our blood sugar increases, and then within 2 to 3 hours blood sugar should return to the level it was before a meal. The amount of sugar in our blood after we eat is called the postprandial blood sugar level. This measurement of blood sugar is also an important indicator of overall health and can be an early sign of abnormal blood sugar control.
Previous studies have identified that clove extract can play a role in helping to manage blood glucose levels. The main objective of this study is to test whether a specialized extract of clove bud, Clovinol®, can help control postprandial blood sugar.

Who can participate?
Individuals who are between 25 and 35 years old, not taking any medication, not obese, and have preprandial (before eating) blood sugar levels below 125 mg/dL.

What does the study involve?
Participants will need to maintain their typical South Indian diet and complete their breakfast by 8 am, eat lunch at 12 pm, and take a Clovinol® capsule immediately after lunch throughout this 30-day study. Between breakfast and lunch, participants should have no snacks or drinks (except water). On specified days of the study, blood sugar will be measured using a digital glucometer immediately before lunch and 2 hours after the start of their lunch.

What are the possible benefits and risks of participating?
Potential benefits include reductions in blood glucose after a meal, which can possibly reduce post-meal fatigue. Potential side effects are limited, but may include mild stomach discomfort.

Where is the study run, and who is funding the study?
This study is funded by and will be conducted at the R&D Center of Akay Flavours & Aromatics Ltd. in Kerala, India.

When is the study starting and how long is it expected to run for?
The study is expected to start in September of 2014 and continue for 30 days.

Who is the main contact?
The main contact is Dr. Krishnakumar IM, Krishnakumar.im@akay-group.com.

Contact information

Type(s)
Public

Contact name
Dr IM Krishnakumar

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683561

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AKCN-CLS_01/14

Study information

Scientific Title
Effects of Clovinol on random blood sugar in healthy and pre-diabetic adults - an open-label pilot study

Study objectives
Type 2 diabetes (T2D) is a global pandemic, and contributes significantly to the increasing incidence of other conditions such as cardiovascular disease. While diabetes screening typically relies on assessment of fasting blood glucose, this may not detect subtle early manifestations of abnormal glucose metabolism. One such early manifestation is impaired glucose tolerance which

can precede T2D by many years and is a risk factor for all-cause mortality. Postprandial plasma glucose measured 2 hours after the start of a meal is a good indicator of the overall status of glucose metabolism. Clove (Syzygium aromaticum L.) and its essential oils (eugenol and acetyl eugenol) have been shown in preclinical studies to modulate pathways involved in glucose metabolism. The objective of this pilot study is to test whether Clovinol could influence glucose metabolism. We will evaluate the effect of Clovinol® supplementation on preprandial glucose levels and 2-h PPG levels in otherwise healthy volunteers who have preprandial glucose levels less than 125 mg/dL. This study will test the hypothesis that daily supplementation with Clovinol will reduce pre- and post-prandial blood glucose by 5 and 40 mg/dL, respectively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sri Rama Hospital ethics committee, 08/08/2014, ECR/184/Indt/KA /2014

Study design
Single-center open-label interventional pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Prediabetes

Interventions
250 mg Clovinol, a hydroethanolic water-soluble exract of unopened clove bud (Syzygium aromaticum L.), administered in one gelatin capsule once daily immediately after lunch for 30 days

Intervention Type
Supplement

Primary outcome measure
Blood glucose measured with a digital glucometer 2 hours after lunch (post-prandial) measured on days 1, 12, 24 and 30. Day 1 is without Clovinol.

Secondary outcome measures

Blood glucose measured with a digital glucometer immediately before lunch (pre-prandial) measured on days 1, 12, 24 and 30. Day 1 is without Clovinol.

Overall study start date
24/03/2014

Completion date
23/10/2014

Eligibility

Key inclusion criteria
1. Healthy
2. Non-obese
3. Aged 25 - 35 years
4. Blood glucose below 125 mg/dL

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
At least ten subjects shall be included in this open label pilot study

Total final enrolment
13

Key exclusion criteria
1. Take any medication
2. Obese
3. Have diabetes

Date of first enrolment
05/09/2014

Date of final enrolment
20/09/2014

Locations

Countries of recruitment
India

Study participating centre
R&D Center, Akay Flavours & Aromatics Pvt Ltd
Ambunadu, Malaidamthirith P O
Ernakulum
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Sponsor information

Organisation
Akay Flavours & Aromatics Pvt. Ltd.

Sponsor details
Malaidamthuruthu P. O., Ernakulam
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Sponsor type
Industry

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/05/2019	09/05/2019	Yes	No