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Bioavailability of oral curcumin ingestion

Submission date 16/03/2017	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 21/03/2017	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 31/07/2018	**Condition category** Other	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Curcumin, a bright yellow spice, is widely grown in South-East Asian countries. It has a long history of use in food as a spice, mainly as an ingredient in many varieties of curry powders and sauces. Curcumin is widely used to colour many foods. Several forms of curcumin are available on the market but their absorption by the body has not been studied for all of the forms. The aim of this study is to measure the absorption of two different curcumin supplements in healthy volunteers.

Who can participate?
Healthy volunteers aged between 18 and 55

What does the study involve?
Participants are randomly allocated to take either a standard curcumin supplement or a new supplement with a glass of water. On the morning of the study, participants arrive having fasted for at least 10 hours. Blood samples are taken before they take the supplement and after 15 minutes, 30 minutes, 1, 2, 3, 4, 5, 6, 8, 12, and 24 hours. Participants record their diet for 3 days before and on the day of the study. A meal not containing curcumin is provided for lunch and dinner on the day of the study. Participants return 7 days later and the process is repeated with the other supplement. Blood samples are tested for levels of curcumin substances and are also stored for potential future testing.

What are the possible benefits and risks of participating?
The results of this study will help people to choose the right supplement for better absorption. A possible risk is pain during the collection of the blood sample.

Where is the study run from?
1. Texas Christian University (USA)
2. University of North Texas Health Science Center at Fort Worth (USA)

When is the study starting and how long is it expected to run for?
June 2016 to August 2017

Who is funding the study?
OmniActive Health Technologies Ltd (India)

Who is the main contact?
Dr Vijaya Juturu

Contact information

Type(s)
Scientific

Contact name
Dr Vijaya Juturu

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CUR004-16

Study information

Scientific Title
A randomized, double-blind, parallel study to compare the relative absorption of UltraSOL Curcumin and Curcumin reference product

Study objectives
Despite its demonstrated effects, the benefit of curcumin is limited by its poor solubility, low absorption from the gut, rapid metabolism and rapid systemic elimination. While the major portion of ingested curcumin is excreted through the feces unmetabolized, the small portion that is absorbed is extensively converted to its water-soluble metabolites, glucuronides and sulfate, and excreted. The purpose of this study was to assess the bioavailability of two different oral curcumin formulations: a curcumin reference (standard) and a new, natural curcumin formulation (UltraSOL Curcumin (OmniActive) over the course of 24 hours (0, 1, 2, 3, 4, 5, 6, 8, 12, 24 hours).

Ethics approval required

Old ethics approval format

Ethics approval(s)
Texas Christian University institutional review board, 07/08/2016, ref: 1605-071-1607

Study design
Single-dose randomized double-blind crossover design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Bioavailability of two different oral curcumin formulations

Interventions
Subjects will be randomised to receive one of two curcumin supplements: Curcumin standard formulation (1800 mg) or UltraSOL Curcumin (376 mg), administered with a glass of water. After a 7-day washout period, this process will be repeated with the other supplement for the two remaining study visits.

On the morning of supplementation, subjects will arrive having fasted for at least 10 hours. A baseline blood sample will be drawn prior to ingestion of supplement (0 hours). Thereafter, blood will be sampled at 15 minutes, 30 minutes, 1, 2, 3, 4, 5, 6, 8, 12, and 24 hours post-ingestion. Subjects will record dietary intake for 3 days prior to and on the day of experimental protocol. A non-turmeric containing meal will be provided for lunch and dinner on the day of experimentation. Subjects will return 7 days after first experimental protocol to participate under alternative treatment. Blood from timepoints (0, 1, 2, 3, 4, 5, 6, 8, 12, 24 hours) will subsequently be measured for curcuminoids (curcumin, demethoxycurcumin, bisdemethoxycurcumin, tetrahydrocurcumin) by HPLC. Blood from timepoints 15 minutes and 30 minutes, as well as additional samples from all other time points will be stored for potential future analysis of free curcuminoids (without the addition of glucuronidase). Descriptive statistics (mean, standard deviation) will be calculated. Area under the curve will be calculated in accordance with the trapezoidal method from 0 to 12 h and 0 to 24 h. Concentration max (Cmax) will be identified as the maximum concentration achieved over the 24 h period with corresponding time (tmax).

Intervention Type
Supplement

Primary outcome measure
Plasma levels of major curcuminoids (curcumin, demethoxycurcumin, bisdemethoxycurcumin and tetrahydrocurcumin) will be evaluated at 0, 1, 2, 3, 4, 5, 6, 8 and 12 hours and 24 h. Peak plasma concentrations (TMax), areas under the plasma concentration-time curves (AUC0-6h, AUC0-12h and AUC0-24h), CMax and t max will be calculated. Relative absorption at 24h time point is helpful to observe normalization and safety of the product

Secondary outcome measures
None

Overall study start date
30/06/2016

Completion date
30/08/2017

Eligibility

Key inclusion criteria
1. Normal healthy individuals
2. Age 18-55
3. Males and females
4. Must be able to perform required testing
5. Participants agreed to sign an informed consent form

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
15

Key exclusion criteria
1. Pregnancy
2. Use of prescription medications
3. Gastrointestinal conditions

4. Diabetics
5. Alcohol and/or substance abuse history, and/or allergies to turmeric or curcumin
6. Subjects consuming any foods or supplements containing curcumin

Date of first enrolment
25/08/2016

Date of final enrolment
30/10/2016

Locations

Countries of recruitment
United States of America

Study participating centre
Texas Christian University
Harris College of Nursing & Health Sciences
Department of Kinesiology
TCU Box 297730
Fort Worth
United States of America
76129

Study participating centre
University of North Texas Health Science Center at Fort Worth
Fort Worth
United States of America
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Sponsor information

Organisation
OmniActive Health Technologies Ltd

Sponsor details
Cybertech House, First Floor
J.B. Sawant Road, Wagle Industrial Estate
Thane
India
400 604

Sponsor type

Industry

ROR
https://ror.org/03fxrgb29

Funder(s)

Funder type
Industry

Funder Name
OmniActive Health Technologies

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jonathan Oliver or Dr Vijaya Juturu

IPD sharing plan summary
Available on request