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Effects of fruit and juices on glucose and insulin

Submission date
24/05/2017

Recruitment status
No longer recruiting

Registration date
08/06/2017

Overall study status
Completed

Last Edited
23/10/2019

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:
There is increasing concern that consumption of free sugars, particularly in the form of sugar-sweetened drinks, may lead to a reduced intake of nutritious foods and increased total calorie intake, leading to an unhealthy diet, weight gain and increased risk of disease. The WHO suggests that the amount of sugar in the diet should drop from 10% to 5% as energy, mainly derived from natural foods such as fruit juices and honey. Fruit juices have a high glycaemic index, meaning that they cause a spike in blood sugar levels. However a recent study showed that fruit juice consumption does not have a significant effect on the fasting sugar and insulin (the hormone which helps the body to process sugar) levels. In addition, the influence of ghrelin (the hormone which makes people feel hungry) on blood sugar control may also be related. There is a lack of studies investigating the effects of different fruit juices on blood sugar and insulin responses at the after meals. Therefore, the aim of the present study is to investigate the effects of fruits, particularly orange and various orange juices on blood sugar and insulin levels immediately after consumption in healthy young adults.

Who can participate?
Healthy adults aged 18-22 of normal weight and obese adults of the same age.

What does the study involve?
All participants attend a total of three study visits on three consecutive days. On the first visit participants consume a raw orange, on the second visit they consume 100% fresh orange juice, and on the third visit they consume nectar sweetened orange juice. Before consuming the drink and then 30, 60, 90 and 120 minutes after, participants have samples of blood collected to test their blood sugar and insulin levels

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
The Doctors Medical Center (United Arab Emirates)

When is study starting and how long is it expected to run for?
July 2016 to July 2020

Who is funding the study?
Zayed University (United Arab Emirates)

Who is the main contact?
Professor Dimitrios Papandreou

Contact information

Type(s)
Scientific

Contact name
Prof Dimitrios Papandreou

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144534

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TDM_25_2015

Study information

Scientific Title
Effects of raw orange, 100% fresh orange juice and nectar sweetened orange juice on plasma blood glucose, insulin and ghrelin levels among normal and obese adults

Study objectives
The nectar sweetened orange juice and the 100% fresh juice will not significantly increase blood glucose and insulin levels post-prandially.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethical Committee of Zayed University and Doctors' Medical Center, 25/11/2016, ref: ZU_081-F and TDMC_25_2015

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Blood glucose levels in healthy people after consumption of fruit or fruit juice

Interventions
10 normal and 10 obese participants attend three study visits on consecutive days.

Visit 1: Participants consume the raw orange
Visit 2: Participants consume 100% fresh orange juice
Visit 3: Participants consume nectar sweetened orange juice

Blood glucose, insulin, and ghrelin will be evaluated at 0, 30, 60, 90 and 120 minutes post-prandially on each study visit.

Intervention Type
Other

Primary outcome measure
1.Plasma Glucose is measured by hexokinase enzymatic method (Cobas, Roche USA) at baseline and 30, 60, 90 and 120 minutes postprandial
2. Plasma Insulin is measured by ECLIA method (Cobas 6000, Roche, USA) at baseline and 30, 60, 90 and 120 minutes postprandial

Secondary outcome measures
Ghrelin levels are measured by immunochemilunometric assay (IDS, SMBH, Germany) at baseline and 30, 60, 90 and 120 minutes postprandial.

Overall study start date
10/05/2017

Completion date
10/06/2017

Eligibility

Key inclusion criteria
Healthy participants:
1. Aged 18-22 years
2. Female
3. Healthy
4. BMI < 25

Obese participants:
1. Aged 18-22 years
2. Female
3. Healthy
4. BMI > 27

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
22 Years

Sex
Female

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Males
2. Aged under 18 and over 22 years
3. Taking medications, supplements
4. Being on a specific diet

Date of first enrolment
15/05/2017

Date of final enrolment

30/05/2017

Locations

Countries of recruitment
United Arab Emirates

Study participating centre
The Doctors Medical Center
Villa T6 Al Batten Street
Khalydia
AbuDhabi
United Arab Emirates
144539

Sponsor information

Organisation
The Doctors Medical Center

Sponsor details
106 Batten Str Khalydia
Abu Dhabi
United Arab Emirates
63086

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
University/education

Funder Name
Zayed University

Alternative Name(s)
ZU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Arab Emirates

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/09/2018

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
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/09/2019	23/10/2019	Yes	No