

Effects of fruit and juices on glucose and insulin

Submission date 24/05/2017	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 08/06/2017	Overall study status Completed	☐ Protocol
Last Edited 23/10/2019	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ 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
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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design

Interventional non-randomised study

Study type(s)

Prevention

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 postprandially on each study visit.

Intervention Type

Other

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

22 Years

Sex

Female

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

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

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