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Effects of tomato-based foods on cardiovascular disease risk

Submission date	Recruitment status	[_] Prospectively registered
10/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/08/2022	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Frank Thies

Contact details
Polwarth Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
+44 (0)1224 553 020
f.thies@abdn.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of a tomato-rich diet on markers of cardiovascular risk in middle aged people: a single centre randomised controlled intervention study

Acronym
LYCTOM trial

Study objectives
10 mg daily lycopene consumption from a high tomato diet or lycopene supplementation can reduce markers for cardiovascular risk in middle aged people.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committees approved on the 23rd May 2007 (ref: 07/S801/32)

Study design
Single centre single blind randomised controlled longitudinal intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Cardiovascular disease risk markers

Interventions
The dietary interventions proposed for this project are designed to compare three diets, each of which are practical and realistic for individuals to achieve. Each dietary intervention will be of 12 weeks duration.

1. Control group (diet limited in tomato-based foods):
The control group will be free to eat normally, but their intake of tomato-based foods will be restricted. They will not be allowed to consume any of the forbidden foods* listed below, but will be allowed to consume up to 1 portion of tomato soup, tomato juice or tomato sauce per

week, and either:
1.1. Up to 4 raw tomatoes/24 cherry tomatoes per week, or
1.2. Up to 1 portion of tomato ketchup per week

2. Tomato group (diet rich in tomato-based foods):
The tomato group will be asked to consume a minimum of 70 mg lycopene per week from tomato-based foods which will be provided, including tomato juice, tomato ketchup, tomato sauce or tomato soup. Guidance will be provided on the number of portions needed to reach the required amount of lycopene intake using a points system. In addition, recipe suggestions can be provided for use of the tomato sauce, e.g. with pasta, with chicken and rice, with vegetables, in a bolognese sauce etc. The consumption of lycopene-equivalent tomato-based food should however not exceed 100 mg per week.

This group will not be allowed to consume any of the forbidden foods*, but will be allowed to consume, in addition to the soups/juices/sauces/ketchup, up to 4 raw tomatoes/24 cherry tomatoes per week.

3. Lycopene group (diet limited in tomato-based foods but supplemented with lycopene capsules):
The lycopene group will be free to eat normally, with the exception of consumption of forbidden foods, but will be supplemented with lycopene capsules (10 mg per day) to match the lycopene intake of the group consuming the tomato-rich foods.

*Forbidden foods:
Passata, canned tomatoes, cooked tomatoes (fried, grilled, etc.), tomato paste, tomato puree, pizza, salsa, chutney, canned beans/spaghetti/ravioli, etc., in tomato sauce, barbeque sauce, brown sauce, pink grapefruit, guava, watermelon, or apricots.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lycopene

Primary outcome measure
Serum total and low density lipoprotein (LDL) cholesterol and intercellular adhesion molecule 1 (ICAM-1) concentrations. All outcomes are measured four times during the study: prior run-in periods, at baseline (after run-in period), after 6 and 12 weeks intervention.

Secondary outcome measures
Insulin sensitivity as well as vascular function and inflammation markers (vascular tonicity by pulse-wave velocity, interleukin-6 [IL-6] and high sensitivity C-reactive protein [hsCRP]). All outcomes are measured four times during the study: prior run-in periods, at baseline (after run-in period), after 6 and 12 weeks intervention.

Overall study start date
01/07/2007

Completion date
31/08/2010

Eligibility

Key inclusion criteria
1. Men and women aged 40 - 65 years
2. Body mass index (BMI) between 25 and 35 kg/m^2
3. Recruited from the surrounding community of Aberdeen
4. Sedentary or moderately active (less than two aerobic session per week)
5. Present signs of metabolic syndrome, e.g., if he/she has three or more of the following conditions:
5.1. Fasting plasma glucose (greater than 6.1 mm/L)
5.2. Triacylglycerol (TAG) level (greater than 1.7 mmol/L)
5.3. Low high density lipoprotein (HDL) cholesterol (less than 1.04 mmol/L for men, less than 1.29 mmol/L for women)
5.4. Hypertension (greater than 130/85 mmHg)
5.5. Central obesity (waist circumference greater than 102 cm for men, greater than 88 cm for women)
5.6. Moderate hypercholesterolaemia

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Cardiovascular disease (CVD)
2. Diabetes
3. Asthma
4. Systolic blood pressure greater than 160 mmHg or diastolic blood pressure greater than 99 mmHg
5. Thyroid gland disorders or eating disorders
6. Regularly taking medication or supplements known to affect any dependant variable measured
7. High habitual intake of tomato-based food (greater than 5 servings per week)
8. Regularly taking nutritional supplements such as antioxidants or fish oil

Date of first enrolment
01/07/2007

Date of final enrolment
31/08/2010

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Polwarth Building
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Polwarth Building
Foresterhill
Aberdeen
Scotland
United Kingdom
AB25 2ZD
-
f.thies@abdn.ac.uk

Sponsor type
University/education

Website
http://www.abdn.ac.uk

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (UK) (ref: NO2038)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2012		Yes	No
Results article		01/08/2022	19/08/2022	Yes	No