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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

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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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.

### Key secondary outcome(s))
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.

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
United Kingdom

Scotland

### Study participating centre
**Polwarth Building**
Aberdeen
United Kingdom
AB25 2ZD

## Sponsor information

**Organisation**
University of Aberdeen (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

**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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |