The protective effect of tomato ketchup consumption on inflammation induced ex-vivo in human blood

Published: 21-10-2011
Last updated: 28-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35235

Source
ToetsingOnline

Brief title
The effect of tomato ketchup on inflammation

Condition

- Other condition

Synonym
Inflammation

Health condition

Inflammatoire biomarkers, zoals cytokinen, chemotaxie en concentratie nutrienten (lycopeen, vitamine C en alpha-tocopherol) in humaan bloed

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: blood, ex-vivo, Inflammation, Tomato ketchup

Outcome measures

Primary outcome

The study parameters are:

a. The release of the cytokines TNF-α, IL-8 and IL-10 from blood upon ex-vivo

stimulation with LPS.

Secondary outcome

The secundairy parameters are:

a. Chemotaxis of monocytes ex-vivo exposed to plasma.

b. Plasma concentrations of lycopene and its stereoisomer, α-tocopherol and

ascorbic acid.

Study description

Background summary

The consumption of tomatoes and tomato products has been associated with a lower risk of developing cardiovascular disease and some types of cancer. Tomatoes and tomato products provide a good source of antioxidants (lipophilic and hydrophilic). Important tomato antioxidants are lycopene, α-tocopherol and ascorbic acid. It has been reported that these antioxidants in isolated form exert directly or indirectly anti-inflammatory effects in vitro.. Studies with tomatoes or tomato products reported that the observed anti-inflammatory effects could not be caused by only a single antioxidant. It was suggested that these effects were due to the combination of antioxidants.
Since, however the relevance of the observed anti-inflammatory effects for humans is entirely unknown the present pilot study aims to assess the acute

effects of a single tomato ketchup consumption on ex-vivo elicited inflammation in a small group of healthy subjects

Study objective

The objectives of the study are to investigate the acute effects of a single consumption of tomato ketchup on ex-vivo elicited inflammation (release of the cytokines TNF-α, IL-8 and IL-10 upon LPS stimulation), chemotaxis of monocytes ex-vivo and on plasma concentrations of lycopene, its stereoisomers, α-tocopherol and ascorbic acid, in healthy subjects.

Study design

The study is designed as a placebo-controlled cross-over trial. After a 3-days run-in period of a diet low in antioxidants, the study parameters will be measured on test day 1 upon a standardized control meal (i.e. the placebo meal) and on test day 2 upon the consumption of 200 g tomato ketchup. For every subject the study lasts in total 5 days.

Intervention

3 Day Run-in period
During the 3-days-run-in period the subjects are instructed to avoid consumption of tomatoes and tomato products, seeds and nuts, egg yolk, all other fruits and vegetables, herbs, spices, ready meals and antioxidant supplements or beverages high in antioxidants (e.g. tea, coffee, chocolate, fruit juices, red wine, beer). Subjects are allowed to eat peeled potatoes, white bread, white pasta, white rice, meat, fish, egg whites, cheese, unflavored yogurt, salt, and pepper. The subjects are allowed to drink ad libitum water, semi-skimmed, or skimmed milk. A similar run-in procedure has been used successfully in a previous study to achieve a low antioxidant background diet and did not cause any adverse effects. Subjects are asked to record their food intake during the run-in period.
On the evening prior to test day 1 (third day of the run-in period) and in the evening of test day 1, the subjects receive a standardized diner . The portion will be 750 g and supplies 5820 kJ (1390 kcal).
After blood collection on test day 1 a standardized lunch will be provided which consists of 2 white bread rolls, with cheese and meat products and 250 g skimmed yoghurt, which will approximately supply 2060 kJ (492 kcal).
During both test days, the subjects are allowed to drink water ad libitum.

Test day 1
On test day 1, all subjects consume a placebo meal with 200 g white cooked rice and a self prepared vinaigrette. The placebo meal consists of approximately 2060 kJ (492 kcal). The vinaigrette is composed in order to

provide the same amounts of macronutrients and caloric value as the tomato ketchup while being free of any antioxidants. The ingredients of the vinaigrette are commercially available at the supermarket.
In the morning of test day 1 the vinaigrette will be freshly prepared by the project leader (M. Hazewindus)

Test day 2
On test day 2 the subjects will consume 200 g tomato ketchup with 200 g white cooked rice, which will supply approximately 2043 kJ (488 kcal). The tomato ketchup is commercially available.

Study burden and risks

Subjects will not have a benefit of a participation in the study.

After signing of the informed consent form, subjects will receive the dietary instructions for the 3 day run-in period, a study diary and 1 standardized dinner for the third evening of the run-in period prior to test day 1. After 22.00 h on the evenings before test day 1 and 2, the subjects are not allowed to eat and drink, with the exception of water. At both test days the subjects will be expected at 7.30 h at the Department of Toxicology at the University of Maastricht, where they will receive the placebo meal (test day 1) or the tomato ketchup meal (test day 2). After consumption of the meal the subjects are free to move within the department. At 14.30 h the subjects are expected back for blood collection in a room being suitable for this purpose. In total 27 ml blood will be collected. This volume of blood is needed to determine the cytokine release upon ex-vivo stimulation with LPS (ca. 10 ml), to assess the chemotaxis of monocytes ex-vivo (ca. 10 ml) and to measure the plasma concentration of lycopene, its stereoisomer*s, α-tocopherol and ascorbic acid by means of HPLC (ca. 5 ml). On test day 1 directly after the blood collection, the subjects receive a standardized lunch which they can immedialty consume. Moreover, they are provided with a second standardized dinner, which they can take home and consume in the evening.

The risk being associated with the blood collection of 27 ml on 2 consecutive days is negligible. Subjects are required to follow a diet low in antioxidants for 3 days. A comparable approach has been applied in a previous study and did not cause any adverse effects. The tomato ketchup is commercially available and is safe for human consumption.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

BMI 20- 30 kg/m2
Age >18 years
No reported physical and/or mental disease(s) or major surgery that might limit participation in or completion of the study
No reported renal and/or cardiovascular disorder(s)/disease(s)
No reported metabolic disorders/diseases in particular no diabetes mellitus type 1 and 2
No use of any medication that is known to influence lipid and glucose metabolism as well as blood pressure from at least one month before beginning of the study until the end of it

Exclusion criteria

Use of any medication (1 month prior to the start of the study and during the study)
Consumption of 3 or more glasses of alcoholic drinks per day
Donation of more than 500 ml blood (<6 months prior to the start of the study)
Vegetarian lifestyle

Allergic to tomatoes or tomato products

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	21-10-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL37566.068.11