Plasma lycopene concentration as a dietary compliance biomarker - a pilot study.

Published:
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Primary objective: to determine if a plasma lycopene concentration can serve as a response parameter after a single dose of dietary lycopene.

Ethical review	Approved WMO
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON57748

Source
ToetsingOnline

Brief title
Lycopene as a dietary compliance biomarker.

Synonym
Not applicable.

Health condition

Geen specifieke aandoening. We zijn benieuwd of lycopeen als een life style compliance marker zou kunnen dienen.

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Erasmus MC Foundation

Intervention

Keyword: Biomarker, Diet, Lycopene

Outcome measures

Primary outcome

Raise of plasma lycopene concentration in absolute (ng/ml) and relative

(percentage of T0-value) after single lycopene intervention.

Secondary outcome

1. Optimal time point of lycopene concentration response after single dietary

intervention (hours, days).

2. Influence of prior food consumption on plasma lycopene levels before and

after lycopene interventions, as measured by dietary questionnaires.

Study description

Background summary

To determine the plasma lycopene concentration before and after an oral intake of lycopene in order to use this measurement as a life style compliance marker.

Study objective

Primary objective: to determine if a plasma lycopene concentration can serve as a response parameter after a single dose of dietary lycopene.

Study design

Cross-over interventional pilot study.

Intervention

Oral food supplement tablet 40 mg lycopene once, versus oral soup of cooked tomatoes equivalent to 40 mg lycopene content. In addition, the participants* habitual diet and actual food intake during the intervention will be measured

using a food frequency questionnaire and a food diary.

Study burden and risks

Eight blood samples of 6 ml full venous blood obtained by vena puncture per intervention per individual, 2 times in a cross-over pilot study, in which interventions are 3 weeks apart (so 2 x 8 samples in 10 volunteers). Risk of vena puncture is negligible, idemque the burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Male;

• Healthy;
• 18-75 yrs old.

Exclusion criteria

• Allergic for tomatoes;
• Any gastrointestinal disorder within 3 months prior to the intervention;
• Recent medication or supplement use;
• Recent substantial change in weight;
• Adherence to a specific diet (e.g., vegan);
• Using recreational drugs more than once a month;
• Smoking and excessive alcohol consumption (>10 standardized glasses a week).
• Risk of a dependency situation with the researchers.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2025
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-06-2025

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL85468.078.23