# Descriptive plasma kinetics of EPA and DHA after administration of a single oral dose of their lysine salts, compared to that after an oral dose of a fish-oil food supplement

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To study and evaluate the plasma concentration-time curves in health young women of free EPA and DHA, as well as those present in a fish oil food supplement (predominantly esterified to glycerol and/or as ethyl-esters) of their esters, following an...

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

## Summary

### ID

NL-OMON46658

**Source**
ToetsingOnline

**Brief title**
Relative oral bio-availability of omega-3 fatty acid lysine salts

### Condition

- Other condition

**Synonym**
n.a. healthy individuals

**Health condition**

voedingsonderzoek

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Wageningen Universiteit
**Source(s) of monetary or material Support:** Evonik Nutrition & Care GmbH

## Intervention

**Keyword:** EPA/DHA, Fish fatty acids, lysine salts of EPA and DHA, Omega-3

## Outcome measures

### Primary outcome

The main study and evaluate parameter is the plasma-time curve of free and

esterified EPa and DHA. This will be studied using descriptive kinetics

(maximum peak height (Cmax), time-to-peak (Tmax), and area-under-the-curve

(AUC)).

### Secondary outcome

The secondary study parameter is the plasma-time curve of satiety hormones

GLP-1, PYY and CCK.

# Study description

### Background summary

Adequate intake of the omega-3 poly-unsaturated fatty acids docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), two fatty acids naturally occurring in oily fish and other marine life, is associated with positive health effects. Recently, a novel molecular form of EPA and DHA has been developed in which the fatty acids are present as their lysine salts. This results in a solid form which offers a number of advantages including greater stability of EPA and DHA, as well as other technological benefits for their application in supplements or other food products. Furthermore, it is hypothesized that DHA and EPA salts are more rapidly, and perhaps more readily, absorbed compared to ethyl-esters or triglycerides, as the free fatty acids are already released from the salts in

the acid environment of the stomach and no hydrolyses is needed. Although this new form has recently been granted GRAS status by the FDA (based on bio-equivalence considerations determined in vitro), its oral bio-availability and plasma kinetics in humans has not been studied in detail yet.

## Study objective

To study and evaluate the plasma concentration-time curves in health young women of free EPA and DHA, as well as those present in a fish oil food supplement (predominantly esterified to glycerol and/or as ethyl-esters) of their esters, following an oral dose of 1400mg of a mixture containing DHA and EPA lysine-salt (AvailOMTM), compared to 1400mg of a mixture of DHA and EPA present as in a commercially available fish oil food supplement (LUCOVITAAL, Puur Koudwater Omega 3 Visolie).

## Study design

This study will have a cross-over design with two test periods of 48 hours

## Intervention

Orale dose of EPA en DHA lysine salts or vis oil food supplementen (containing EPA en DHA).

## Study burden and risks

Consumption of EPA / DHA, either as glycerol-esters, ethyl-esters (e.g. the medicinal product OmacorR), phospholipids (predominantly present in algae oils) or in their free carboxylic form (EpanovaR) is common in humans and considered to deliver health benefits. In the new salt formulation studied here, the counter ion is lysine, which is an amino-acid that is abundantly present in the diet and the human body. The test product has received an FDA no objection letter. It is conceivable and supported by in vitro studies involving digestion models that dissociation of the salt will rapidly occur in the stomach and that fatty acids will become available for absorption starting from the proximal site of the GI tract (duodenum). Compared to some forms of n-3 fatty acids, in particular the esters, some differences in absorption kinetics might be envisaged, since the latter ones require hydrolysis by lipases in the gastro-intestinal tract. Furthermore, due to interactions with nutrient-sensing receptors at other than usual locations, a different time-profile of satiety hormones might result. The product has been designed to formulate omega-3 preparations with improved properties. Participants contribute to scientific research and they will receive a financial compensation of ¤500,- when completing the whole study. The placement of venous catheters and blood sampling will lead to mild discomfort. The ingestion of the two preparations might lead to side effects, among which gastrointestinal abnormalities (e.g.

burping). Lastly, the overnight stay at our research facilities will be a small burden.

## Contacts

**Public**
Wageningen Universiteit

Stippeneng 4
Wageningen 6708WE
NL
**Scientific**
Wageningen Universiteit

Stippeneng 4
Wageningen 6708WE
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

* BMI between 18.5 and 25 kg/m2
* Age is between 18 and 28 years
* Good general health
* Female
* Veins suitable for blood sampling

### Exclusion criteria

* Current diseases
* Any gastrointestinal conditions/diseases within the 3 months prior to the intervention
* Haemoglobin (Hb) level < 7.5 mmol/L
* Use of medication two months before and during the intervention, except for oral contraceptives and occasional use of NSAID (<1 NSAID per week average).
* (If applicable) In case of using contraceptives, not willing to delay the break between two packets of the conception pill during which a woman gets her period during the study period.
* Reported weight loss or weight gain of > 2 kg in the month prior to the intervention
* Use of omega-3 or fish oil supplements, 3 weeks before-, or during the intervention.
* Not willing to eat fish oil products or animal products
* Allergies to (shell)fish or soy products.
* Allergies to gluten or milk product.
* Following a certain diet
* (History of) drug abuse, in this case meaning >1 x per month use of recreational drugs
* Smoking
* Alcohol consumption of >10 standardised glasses per week.
* Recent or planned blood donation (<4 month prior to first study day or during intervention)
* Have been pregnant or breastfeeding in the last 6 months, or plan to become pregnant during the study
* Personnel of Wageningen University, department of Human Nutrition, their partner and their first and second degree relatives
* Current and within 1 month of participation in other scientific research (apart from EetWeetMeet)
* Not having a general practitioner

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 19-06-2018 |
| Enrollment: | 8 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 28-05-2018 |
| Application type: | First submission |
| Review commission: | METC Wageningen Universiteit (Wageningen) |

## 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 | NL63619.081.18 |