

# The importance of the arachidonic acid /eicosapentaenoic acid (AA/EPA) ratio and omega-3 index on the incidence of running-related injuries

<b>Submission date</b> 16/12/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/03/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/05/2023	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Background and study aims.

Running is one of the most common kind of exercise among athletes. A "runner" is generally defined as a person who runs a minimum distance of about 20-30 km per week, from a period of time ranging between 1 and 3 years. However, both amateur and professional athletes are largely affected by overuse injuries at different districts. After intense physical exercise or after injury, an inflammatory process occurs. The activation and the subsequent inflammation resolution are necessary processes to start tissues healing. Since distinct lipid mediators can be synthesized from omega-6 ( $\omega$ -6) and omega-3 ( $\omega$ -3), pro-inflammatory and pro-resolving lipid mediators respectively, the scientific community focused on the possible efficacy of the polyunsaturated fatty acids omega-6 ( $\omega$ -6) and ( $\omega$ -3) in the modulation of inflammatory processes. Furthermore, it is questioned if an imbalance of  $\omega$ -6/ $\omega$ -3 fatty acids can result in a higher incidence of overuse injuries in runners. The aim of this study is to evaluate whether the arachidonic acid/eicosapentaenoic acid ratio (AA/EPA) or the deficiency of  $\omega$ -3 index is related to an increased risk of overload injury ("overuse", bone microfracture, muscle or tendon rupture) in this population of athletes.

Who can participate?

Healthy runners and triathletes, males and females, who usually train at least 2 times per week from at least 12 months

What does the study involve?

Previously collected data is collected from a database. A statistical analysis to evaluate the potential association between fatty acid composition and risk of injuries.

What are the possible benefits and risks of participating?

By taking part in this study there are no risks of physical injury or harm. The anonymity of the participants was guaranteed.

Where is the study run from?

1. Sannio Tech Consortium (Italy)
2. Sport Campus of Varese (Italy)

When is study starting and how long is it expected to run for?

September 2016 to December 2017

Who is funding the study?

Investigator initiated and funded (Italy)

Who is the main contact?

Dr Giovanni Scapagnini

giovanni.scapagnini@unimol.it

## Contact information

### Type(s)

Scientific

### Contact name

Prof Giovanni Scapagnini

### Contact details

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Italy

86100

## Additional identifiers

### Protocol serial number

NO. Rf. 200617

## Study information

### Scientific Title

Long-chain omega-3 fatty acids and incidence of running-related injuries: an observational study on the role of AA/EPA ratio and omega-3 index

### Study objectives

Considering that the activation and the resolution of the inflammation have a fundamental role in the recovery of an injured tissue, this retrospective observational study verified whether an imbalance of the AA/EPA ratio and an altered  $\omega$ -3 index can be related to an increased risk of overuse injury in runners and triathletes. In particular, this study was designed to evaluate the link between variation of these parameters (AA/EPA ratio;  $\omega$ -3 index) and the risk of injury associated with training load and athletes characteristics.

### Ethics approval required

Old ethics approval format

**Ethics approval(s)**

Insubria Ethical Committee, 29/09/2017, ref: 10.2692017

**Study design**

Retrospective observational

**Primary study design**

Observational

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Running-related injuries

**Interventions**

The study includes a retrospective statistical analysis of clinical, laboratoristic and sports practice data of 275 runners and triathletes.

Participants completed a questionnaire that allows researchers to collect the following information:

1. Anthropometric characteristics
2. Potential use of anti-inflammatory drugs and/or  $\omega$ -3 food supplements
3. Years of training
4. Hours of physical activity performed weekly
5. Kilometers of run weekly
6. Any overuse injuries occurred in the last 6 months.

Dried whole blood spot samples, obtained using lancet finger sticks, are collected to perform lipidomic analysis using gas chromatography-mass spectrometry. The  $\omega$ -3 PUFAs that are quantified, including ALA, EPA, DHA, and docosapentaenoic acid (DPA). The  $\omega$ -6 PUFAs are also quantified, including linoleic acid (LA) and arachidonic acid (AA). Explorative bivariate statistical analyses are performed to investigate the possible association and confounding role of each variable considered. Chi-squared test, Spearman correlation coefficient, Wilcoxon- Mann-Whitney and Kruskal-Wallis tests are used for categorical, continuous variables and continuous on categorical variables, respectively. The association between the AA/EPA ratio,  $\omega$ -3 index and the other covariates are assessed by using the linear regression model. The association between the risk of injuries, the AA/EPA ratio,  $\omega$ -3 index and the other covariates are assessed by using the logistic model. The results of the statistical modelling are considered statistically significant whenever a 2-sided P value less than 0.05 was achieved.

**Intervention Type**

Other

**Primary outcome(s)**

1. Potential association between alterations of AA/EPA ratio and risk of running-related injuries.
2. Polyunsaturated fatty acids (PUFAs) [EPA, AA, and DHA] were measured using gas chromatography.

**Key secondary outcome(s)**

Possible association between the value of  $\omega$ -3 index and risk of running-related injuries. The levels of PUFAs to determine  $\omega$ -3 index were measured using gas chromatography.

**Completion date**

15/12/2017

**Eligibility****Key inclusion criteria**

1. Healthy Caucasian males and females
2. Runners or triathletes
3. Age  $\geq$ 18 years
4. Subjects who did not participated in similar studies in the last 3 months
5. Absence of eating disorders
6. Subjects informed about the procedures and who have signed an informed consent appropriately prepared by the proponents
7. Subjects usually train at least 2 times a week for at least 12 months

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

275

**Key exclusion criteria**

1. Subjects that do not meet the inclusion criteria
2. Currently pregnant

**Date of first enrolment**

10/01/2017

**Date of final enrolment**

30/09/2017

**Locations****Countries of recruitment**

Italy

**Study participating centre**

**Sannio Tech Consortium**

Italy

82030

**Study participating centre**

**Sports Medicine Campus of Varese**

Italy

21100

## Sponsor information

**Organisation**

Equipe Enervit srl

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Giovanni Scapagnini, University of Molise Department of Medicine and Health Sciences at [g.scapagnini@gmail.com](mailto:g.scapagnini@gmail.com) or [giovanni.scapagnini@animol.it](mailto:giovanni.scapagnini@animol.it)

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		25/10/2021	26/10/2021	Yes	No

[Results article](#)

26/04/2019

19/05/2023

Yes

No