

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

Submission date 16/12/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/03/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 19/05/2023	Condition category Injury, Occupational Diseases, Poisoning	<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 (ω -6) and omega-3 (ω -3), pro-inflammatory and pro-resolving lipid mediators respectively, the scientific community focused on the possible efficacy of the polyunsaturated fatty acids omega-6 (ω -6) and (ω -3) in the modulation of inflammatory processes. Furthermore, it is questioned if an imbalance of ω -6/ ω -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 ω -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

Via de sanctis snc III Edificio Polifunzionale University of Molise

Campobasso

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86100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 ω -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; ω -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

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 ω -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 ω -3 PUFAs that are quantified, including ALA, EPA, DHA, and docosapentaenoic acid (DPA). The ω -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, ω -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, ω -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 measure

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.

Secondary outcome measures

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

Overall study start date

30/09/2016

Completion date

15/12/2017

Eligibility

Key inclusion criteria

1. Healthy Caucasian males and females
2. Runners or triathletes
3. Age ≥ 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

275

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

Sponsor details

Via Garavaglia, 2

Zelbio (CO)

Italy

22020

Sponsor type

Not defined

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

01/09/2018

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 or giovanni.scapagnini@unimol.it

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/10/2021	26/10/2021	Yes	No
Results article		26/04/2019	19/05/2023	Yes	No