The protective effect of Masquelier*s® French Pine Bark Extract with Original OPC in half-marathon runners using a single low dose of ibuprofen

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In the present study we aim to assess the efficacy of a 14-days intervention with monomeric and oligomeric flavanols from Vitis vinifera seeds and Pinus pinaster bark (MOF-VVPB) which are the active principle in Masquelier*s® French Pine Bark...

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

Summary

ID

NL-OMON45867

Source
ToetsingOnline

Brief title
Monomeric and oligomeric flavanols in half-marathon runners

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
NSAIDs related kidney injury, running related kidney injury

Health condition

hardlopen geassocieerde aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,I.N.C. Agency B.V.

Intervention

Keyword: Ibuprofen, Kidney function, Monomeric and oligomeric flavanols, Running

Outcome measures

Primary outcome

Main study parameter will be improved resistance to acute kidney damage as assessed by reduction of the neutrophil gelatinase-associated lipocalin (NGAL) concentration in urine.

Secondary outcome

The secondary study endpoints will include evaluation of:

* kidney function assessed by urinary concentration of cystanin C, creatinine, urea, uric acid, Na+, Cl-, K+, glucose, beta-2microglobulin, albumin, albumin/creatinine ratio, urinary osmolality.

* urinary inflammatory parameters such as tumor necrosis factor-alpha (TNF-*), interleukin (IL)-6, IL-8 and IL-18.

* urinary parameters for oxidative stress such as malondialdehyde (MDA) and trolox equivalent antioxidant capacity (TEAC).

* bilirubin, protein, erythrocytes, glucose, ketones, leukocytes, nitrite, pH, urobilinogen, specific gravity by urine dipstick.

* urinary concentration of the extracellular vesicles.

Study description

Background summary

Running is associated with a healthy life style and improved quality of life. At the same time, participation in vigorous exercise such as marathon can be accompanied by significant shift in the health biomarkers and development of transient kidney damage. This risk may be potentiated by intake of nonsteroidal anti-inflammatory drugs (NSAIDs). It has been shown that development of oxidative stress, endothelial dysfunction and pro-inflammatory state play an important role in the pathogenesis of acute kidney damage associated with the endurance running. Monomeric and oligomeric flavanols (MOF) are well characterized for their antioxidant, anti-inflammatory effects as well as pleiotropic beneficial actions on the vascular function. However, the potential protective influence of MOF on the kidney function in the half-marathon runners taking a single low-dose of ibuprofen has not been investigated.

Study objective

In the present study we aim to assess the efficacy of a 14-days intervention with monomeric and oligomeric flavanols from Vitis vinifera seeds and Pinus pinaster bark (MOF-VVPB) which are the active principle in Masquelier*s® French Pine Bark Extract with Original OPCs on the parameters of renal injury, urinary biomarkers of inflammation and oxidative stress in recreational runners who run a half-marathon and take a single low-dose dose of ibuprofen prior to the start.

Study design

Double-blind, randomized, placebo-controlled, pilot study.

Intervention

Subjects will be randomly allocated into two groups and administered either two capsules of MOF-VVPB or placebo twice a day for 14 days before the participation in the half-marathon preceded by the intake of a single low dose of ibuprofen.

Study burden and risks

The risk associated with the participation in this study will be related to intake of the investigational product MOF-VVPB, participation in the half-marathon and use of a single low dose of ibuprofen. Oral consumption MOF-VVPB is generally well tolerated and has not been associated with

significant side effects except mild gastrointestinal discomfort in some of the previous studies. At the same time, it may offer protection against the kidney injury due to vasoprotective, antioxidant and anti-inflammatory effects. Participation in the half-marathon carries risk of exercise-induced injuries, dehydration, electrolyte imbalance, acute kidney injury and, in rare cases, myocardial infarction and exercise-related death. Intake of NSAIDs to prevent exercise related pain and improve performance may increase the risk of acute kidney injury and gastrointestinal dysfunction in runners. But there is no clear evidence that administration of a single low-dose ibuprofen and running 21.1 km may exert significant hazardous effects on the kidney function.

The results of this study will provide information whether the intake of the monomeric and oligomeric flavanols can reduce the risk of kidney damage, improve resistance to oxidative stress and excessive inflammatory response associated with running half-marathon and preventive use of NSAIDs. This will be important for the design of the future trials aiming to develop recommendations on nutrition and use of dietary supplements in physically active individuals. Moreover, the study will improve our understanding of the risk imposed by preventive use of low-dose ibuprofen and running half-marathon distance. In the longer perspective, this research will contribute to increase in the overall safety of the commonly practiced life style - recreational running.

The procedures involved in this study will include interview, assessment of the vital signs, completion of the study related questionnaires and collection of the urine samples before and after use of low-dose ibuprofen followed by the half-marathon. No other procedures including invasive ones will be involved. Runners will receive a unsubstantial financial reward as a benefit for the participation in this study.

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

1. Signed informed consent prior to initiation of any study related procedures.
2. Healthy male and female recreational runners above 18 years of age.
3. Presence of at least 2 years of running experience.
4. Self-reported use of pain killers before/during at least two previous running events.
5. Normal constant eating habits during at least 3 months prior to inclusion into the study.

Exclusion criteria

1. Participation in another marathon or half-marathon within last 4 weeks prior to inclusion into this study.
2. Regular use of NSAIDs within 4 weeks prior to inclusion into this study.
3. Donation of blood within 8 weeks prior to the inclusion into this study.
4. Use of drugs that lower blood pressure and impair renal autoregulation (e.g. angiotensin converting enzyme inhibitors, angiotensin II receptor blockers, diuretics), anabolic steroids or other stimulants or drugs largely influencing glucose and lipid metabolism within 4 weeks prior to inclusion into this study.
5. History of hypothyroidism, chronic kidney or/and liver disorders, coronary artery disease, malignant hypertension, seizures.
6. Active smoking within the last 6 months prior to inclusion into this study.
7. Viral or bacterial infection requiring use of antibiotics, laxatives and anti-diarrhoeal drugs within 4 weeks prior to inclusion into this study.
8. Use of dietary supplements with potential effects on antioxidant or inflammatory status or with potential renoprotective effects within 4 weeks prior to inclusion into this study.
9. Vegetarian or vegan life-style.
10. Excessive alcohol consumption (> 28 consumptions approx. 250 g alcohol per week).
11. Use of a medically prescribed or slimming diet.
12. Any major running injuries over past 3 months prior to the baseline assessments.

13. Participation in a clinical trial within 4 weeks prior to inclusion into this study.
14. Pregnancy and/or breastfeeding.
15. Psychotic, addictive or other mental disorder limiting the ability to provide informed consent or to comply with the study requirements.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2018
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-10-2018
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL65544.072.18