The effect of a combination of orange- and pomegranate actives on physical fitness in elderly people

Published: 14-02-2018
Last updated: 12-04-2024

The primary objective of this study is to determine the effect of daily supplementation of a combined orange- and pomegranate extract for a period of 4 weeks on physical fitness compared to placebo.

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

Summary

ID

NL-OMON46427

Source
ToetsingOnline

Brief title
Actiful

Condition

- Other condition

Synonym
performance, physical fitness

Health condition

fitheid

Research involving
Human

Sponsors and support

Primary sponsor: Bioactor BV
Source(s) of monetary or material Support: BioActor B.V.

Intervention

Keyword: Fitness, Orange, Polyphenols, Pomegranate

Outcome measures

Primary outcome

Main endpoints are distance covered during a 6 minute walk test (6 MWT)

Secondary outcome

Secondary endpoints include the quality of life, as measured by the WHOQOL-BREF questionnaire, lower body strength as measured by the 30s chair stand test, upper body strenght as measured by an arm curl test, lower body flexibility as measured by a chair sit and reach test, upper body flexibility as measured by a back scatch test, heart rate (HR) in rest and during a 6 minute walk test, daily physical activity measured with accelerometer, and blood parameters of antioxidative capacity and inflammation.

Study description

Background summary

Dietary habits and physical activity are two important components of a healthy lifestyle. Targeted nutritional interventions may improve health and stimulate physical activity. Both orange extracts and pomegranate concentrate have been shown to exert beneficial effects on health and exercise performance. However, the effects of a combination of the two extracts on exercise and physical activity have not been investigated yet. It is expected that this combination may be an effective dietary way to improve exercise performance, physical activity in the free-living state, and quality of life in a middle aged

population.

Study objective

The primary objective of this study is to determine the effect of daily supplementation of a combined orange- and pomegranate extract for a period of 4 weeks on physical fitness compared to placebo.

Study design

The design conforms to a randomized, double-blind, placebo-controlled cross-over design

Intervention

In this crossover study, participants will daily receive either a placebo or Actiful®, a supplement containing 500 mg orange extract and 200 mg pomegranate actives, for 4 weeks followed by a wash-out period of 4 to 8 weeks. Subsequently, the second intervention period of 4 weeks (active product or placebo) will take place. The product and placebo will be supplied in capsules that participants can ingest with a glas of water (daily, prior to breakfast).

Study burden and risks

In total, participants will visit the site 5 times, (one screening, 4 test days), resulting in a time investment of approximately 10 hours. During the study participants will have to answer questionnaires about (general) health status and Quality of Life, and have to undergo several tests to determine physical fitness. Furthermore they will have to keep food and activity records and wear an accelerometer the week prior to each test day. A maximum of 39.8 ml of blood will be collected each test day.

Contacts

Public
Bioactor BV

Oxfordlaan 70
Maastricht 6229EV
NL
Scientific
Bioactor BV

Oxfordlaan 70

Maastricht 6229EV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy male/female (based on medical history provided during a general health questionnaire); Age between 60 * 75

Exclusion criteria

- Allergy to test product/placebo
- Allergy to citrus fruits
- BMI lower than 18 or higher than 28
- Recent muscle injury in less than one month before the start of the study.
- Medical conditions that might influence outcome measure or participant safety during testing, including but not limited to: severe cardiovascular disease, cancer, Parkinson*s disease. To be decided by PI.
- High blood pressure (systolic * 140 mmHg, diastolic * 90 mmHg (40)
- Use of medication that may interfere with the study results
- Smoking
- Administration of investigational drugs or participation in any scientific intervention study which may interfere with this study (to be decided by the principle investigator), in the 180 days prior to the study.
- Abuse of products; alcohol (> 20 alcoholic units per week) and drugs.
- Unable to correctly perform the tests during the familiarization test

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2018
Enrollment:	37
Type:	Actual

Ethics review

Approved WMO

Date:	14-02-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL63326.068.17
Other	volgt nog

Study results

Date completed:	17-01-2019
Actual enrolment:	37