The effect of 12-week supplementation with AstaPure® on skin-aging and muscle function in postmenopausal women (<=70 y)

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

Summary

ID

NL-OMON57297

Source
ToetsingOnline

Brief title
MISSION study

Condition

- Other condition

Synonym
menopause

Health condition

post-menopause symptoms

Research involving

Human

Sponsors and support

Primary sponsor: BioActor BV (Solabia Nutrition)
Source(s) of monetary or material Support: BioActor BV

Intervention

Keyword: Astaxanthin, menopause, muscle function, skin health

Outcome measures

Primary outcome

The effects of AstaPure® Oleoresin on skin health levels will be assessed by measuring transepidemial water loss (TEWL). TEWL provides information on the integrity of the skin's protective barrier functions. The measurements are performed by the application of a probe to the skin surface for 30 seconds. Upon contact, the water evaporation rate (g/h/m²) is obtained. High values of TEWL reflect a damaged skin barrier function.

Secondary outcome

The effects of AstaPure® Oleoresin on skin health levels will be furthermore assessed by skin microbiota swaps and skin markers on tape-strips (e.g., collagen). In addition, other skin, hair and nail parameters will be assessed such as wrinkles, hydration, pigmentation, erythema, hair density and hair diameter. An additional endpoint is to assess the effect of AstaPure® on muscle related outcomes (handgrip strength, arm curl test, sit to stand test). In a subgroup, an exploratory outcome is to investigate the effect on extracellular matrix (ECM) in skeletal muscle biopsies.

Study description

Background summary

Changes in the appearance and function of the skin are a general phenomenon in old age. Additionally, age-related loss of skeletal muscle mass and function affects up to 27% of elderly individuals. Both skin and muscle mass changes are affected, amongst others, by the hormone estrogen. Hypoestrogenism exacerbates the effects of aging and contributes to a higher incidence of sarcopenia in postmenopausal women. Multiple animal and human studies have shown that astaxanthin (present in microalgae) may improve skin function by decreasing transepidemial water loss (TEWL). In addition, the antioxidative effects of astaxanthin may improve muscle function of postmenopausal women.

Study objective

The primary objective is to examine the effect of twelve weeks supplementing daily one AstaPure® Oleoresin capsule on trans epidermal water loss (TEWL) in postmenopausal women. The secondary objectives are to investigate the effects on other skin, hair, and nail parameters and muscle function. An exploratory outcome is to investigate the effect of AstaPure® on extracellular matrix (ECM).

Study design

A parallel, double-blinded, randomized controlled trial will be carried out. The intervention period will last for twelve weeks.

Intervention

Participants will ingest daily with breakfast 80 mg microalgae oleoresin or rapeseed oil in the form of capsules for 12 weeks.

Study burden and risks

Total study duration will be 12 weeks (and 9 additional days when participating in the sub study). During the study blood samples will be collected (73.5 mL mL in total), which occasionally may cause a hematoma or bruise. For participants taking part in the sub study, three muscle biopsies and a bout of eccentric muscle damaging exercise will be performed, which will cause muscle soreness afterwards. Other measurements are not expected to cause side effects. Subjects will have a total time investment of ±6.5 h for the main study and ±11 h for taking part in the explorative substudy.

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

Postmenopausal women (amenorrhea over 12 months)

Age <=70 years old

Exclusion criteria

Allergy to test product/control

Use of hormone replacement therapy (estrogenic or progestogenic) in the past 3 months before TD1

Use of probiotics or supplements containing vitamins, minerals or antioxidants four weeks prior T1 (Calcium and vitamin D supplementation are permitted)

Use of antibiotics within 3 months prior to TD1

Having donated blood within one month before the start of the study, or planning to donate blood during the study

Regular smoking on a weekly or biweekly basis (including use of e-cigarettes)

Abuse of alcohol (alcohol consumption >20 units/week) and/or drugs

Regular strength or endurance exercise e.g. muscle strengthening exercises in the gym or improving aerobic capacity such as running, mountain biking, swimming (>= 3 times per week) performed within six months prior to the study

Intention to take part in any weight loss program

Underwent Botulinum toxin A (Botox) injection treatment near the test sites within 2 years of baseline or plan to receive this treatment during the study

Underwent Filler injection (collagen, hyaluronic acid, etc.) near the test sites within 2 years of baseline or plan to receive this treatment during the study

Not willing to avoid over-exposure to sun or tanning session (solarium) on the test area within 30 days before the study starts and for the duration of the study (exposure after application of sunscreen allowed)

Willing not to change the routine use of facial cream/treatment during the study duration

Treatment with an investigational drug (phase 1-3) 180 days before the start of the study

Diagnosed with medical conditions that might interfere with endpoints or compromise participant safety during testing (e.g. skin diseases, cancer, Gastrointestinal diseases or abdominal surgery interfering with gastrointestinal function, diabetes, coronary heart disease, hypertension >160/100mmHg, coagulation disorders, moderate to severe osteoarthritis of the knee) is to be decided by the principal investigator

Medication intake that might interfere with endpoints or compromise participant safety during testing (e.g. Glucose-Lowering Medications such as Metformin or Topical treatment with corticosteroids around the tested area, NSAIDs, angiotensin-converting enzyme (ACE) inhibitors, and statins) to be decided by the principal Investigator

Recent skeletal muscle injury less than one month before the start of the study

Inability to understand study information and/or communicate with staff

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-12-2024
Enrollment:	43
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	13-02-2025
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
ClinicalTrials.gov	NCTnognietbekend
CCMO	NL86813.068.24