

Effects of omega-7 sea buckthorn oil capsule on mucous membranes of post-menopausal women [omega 7-tyrniöllykapseleiden käyttö vaihdevuosisoireiden, emättimen ja muiden limakalvojen kuivuuden ja virtsatieoireiden hoidossa]

Submission date 15/08/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/08/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/08/2008	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Baoru Yang

Contact details

Aromtech Ltd
Tykistökatu 4 D (DIO)
Turku
Finland
20520

Additional identifiers

Protocol serial number

SBRE2008

Study information

Scientific Title

Acronym

SBMUCOS2008

Study objectives

Increased oxidative stress to the secretion glands and the cells of mucous membranes is part of the mechanism of ageing-related dryness and inflammation in the mucous membranes of female subjects. Sea buckthorn oil supports the health of mucous membranes by supplying the body with lipid nutrients required for maintaining the structure and function and for regeneration of mucous membranes. High content of antioxidants in sea buckthorn oil will increase the antioxidant capacity and reduce lipid peroxidation of plasma. Supplementation with sea buckthorn oil will decrease the plasma C-reactive protein (CRP) level indicating reduced inflammation in the body.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Ethical Committee of the Hospital District of Southwest Finland on the 5th August 2008 (ref: 7/2008 § 254).

Study design

A randomised, double blind, placebo-controlled, single-centre parallel study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mucosa membrane dryness

Interventions

Group one: omega 7 capsules 2 x 2 capsules per day for 4 months

Group two: placebo capsules (medium chain triglycerides), 2 x 2 capsules per day for 4 months

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sea buckthorn oil

Primary outcome(s)

1. Dryness, itching, pain, burning and/or inflammation in the mucosa of the genital tract at baseline, after one and four months of supplementation
2. Vaginal PH at baseline, after one and four months of supplementation
3. Maturation index of vaginal mucosa at baseline, after one and four months of supplementation

Key secondary outcome(s)

1. Plasma total antioxidant capacity at baseline, after one and four months of supplementation
2. Plasma isoprostane level at baseline, after one and four months of supplementation
3. Plasma C-reactive protein level at baseline, after one and four months of supplementation

Completion date

30/03/2009

Eligibility**Key inclusion criteria**

1. Healthy post-menopausal females aged 55 - 70 years
2. Dryness, itching, pain, burning and/or inflammation in the mucosa of the genital tract
3. Problem of the genital tract mucosa shall not have clear association with severe diseases

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Severe diseases and/or receiving systematic medications such as hormone replacement therapy, anti-inflammatory and cholesterol lowering drugs
2. Diabetes
3. Hormonal, renal, haematological, or hepatic dysfunction

Date of first enrolment

18/08/2008

Date of final enrolment

30/03/2009

Locations**Countries of recruitment**

Finland

Study participating centre
Aromtech Ltd
Turku
Finland
20520

Sponsor information

Organisation
Turku University Central Hospital (Finland)

ROR
<https://ror.org/05dbzj528>

Funder(s)

Funder type
Government

Funder Name
Finnish Funding Agency for Technology and Innovation (TEKES) (Finland)

Funder Name
Aromtech Ltd (Finland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes