ISRCTN91680999 https://doi.org/10.1186/ISRCTN91680999

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

Submission date	Recruitment status	[_] Prospectively registered
15/08/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/08/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
21/08/2008	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
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

Secondary outcome measures
1. Plasma total anoxidative 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

Overall study start date
18/08/2008

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

Age group
Senior

Sex
Both

Target number of participants

100

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)

Sponsor details
c/o Risto Erkkola
Department of Gynecology
TYKS, PL 52
Turku
Finland
20521

Sponsor type
Hospital/treatment centre

Website
http://www.tyks.fi

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration