

Potential antioxidant effects of a natural clinoptilolite zeolite/sea buckthorn (ZSB) dietary supplement on smokers with stressful life styles

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Registration date 26/02/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/05/2022	Condition category Mental and Behavioural Disorders	<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

Background and study aims

Zeolites are unique, natural volcanic minerals. They have antioxidant and antiviral properties and act as natural “magnets” that absorb and remove toxins, such as heavy metals, chemicals and pollutants from the body. Sea Buckthorn oil is a herb rich in antioxidants (due primarily to its high flavonoid and vitamin C content), essential amino acids and omega 7. Studies have shown it to lower cholesterol and improve heart function in people with coronary heart disease. The aim of this study is to examine the potential antioxidant effects of a natural clinoptilolite zeolite/sea buckthorn (ZSB) dietary supplement on smokers with stressful life styles.

Who can participate?

Healthy Caucasian adults that smoke, consume a unhealthy diet, have stressful office jobs and physically inactive.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group A (control group) are given a placebo three times a day for 3 months. Those in group B (study group) are given the ZSB dietary supplement (600 mg of natural clinoptilolite zeolite and 150 of sea buckthorn, three times a day for 3 months). Blood samples are taken before start of the study and at the end. Participants are also followed up on regular intervals (every 15 days) during the study period.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

General State Hospital of Athens and Laiko Hospital, Athens (Greece)

When is the study starting and how long is it expected to run for?

January 2014 to March 2015

Who is funding the study?
Medicines from Earth LTD (Bulgaria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZSB/CA-2015-1

Study information

Scientific Title
Potential antioxidant effects of a natural clinoptilolite zeolite/sea buckthorn (ZSB) dietary supplement on smokers with stressful life styles: a prospective, randomized case control study.

Study objectives
We examined the potential antioxidant effects of a natural clinoptilolite zeolite/sea buckthorn (ZSB) dietary supplement on smokers who were consuming non-healthy food and exhibited a stressful life style.

Ethics approval required
Old ethics approval format

Ethics approval(s)

General state hospital of Athens- ZSB/2014, ref: 1089

Study design

Prospective, randomized case control study.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

We have examined the antioxidant status of healthy volunteers who were smokers, followed an unhealthy diet as defined by the consumption of junk food at least 3 times per week and were doing stressful (office) jobs. The subjects reported also minimal levels of physical exercise as defined by walking less than one mile per day.

Interventions

Upon inclusion, patients were randomized to Group A (controls, 25 subjects) who were receiving a placebo and Group B (study group, 25 subjects) who were receiving the ZSB dietary supplement (600 mg of natural clinoptilolite zeolite and 150 of sea buckthorn, three times/day). Block randomization was performed to ensure equal number of patients in the two groups.

Intervention Type

Supplement

Primary outcome measure

To evaluate the anti-oxidant properties of ZSB by measuring the total antioxidant status (TAS) and the thiobarbituric acid reactive substances (TBARS) test in cases and controls.

Secondary outcome measures

1. Any potential side effects following the administration of ZSB. Patients were followed every 15 days by means of total blood counts and regular biochemical studies including urea, creatinine, and hepatic enzymes
2. Patient self-evaluation (via a questionnaire) of any potential changes in their smoking/dietary habits, level of physical activity (walking miles per day) and stress levels. Stress levels were assessed by means of a semi-quantitative scale (1 to 10; whereas 1 indicated no stress and 10 high stress levels).

Overall study start date

01/01/2014

Completion date

01/03/2015

Eligibility

Key inclusion criteria

1. Healthy Caucasian volunteers (20 males, 37 ± 6.3 year old, with body mass index (BMI) 28.2 ± 1.6) who were following a non-healthy type of diet as defined by the consumption of junk food at least 3 times on a weekly basis were recruited from a relatively young population of patients who have been visiting during 2014 an outpatient medical clinic of a university hospital for routine check-up purposes
2. All patients were smokers ($15 \text{ packs. yr} \pm 2.7$)
3. All were doing stressful (office) jobs
4. Level of physical exercise was minimal as defined by walking less than a mile/day
5. All patients provided formal informed consent to participate in the study which was approved by the institutional ethics committee

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

50

Key exclusion criteria

1. Any recorded active medical disorder
2. History of cardiovascular disease or any other systemic inflammatory disorder
3. Abnormal lipid blood profiles
4. Age over 65 years old

Date of first enrolment

01/01/2014

Date of final enrolment

01/01/2015

Locations

Countries of recruitment

Greece

Study participating centre

General State Hospital of Athens

154 Mesogeion Avenue

Athens
Greece
11527

Study participating centre

Laiko Hospital
Agiou Thoma 17
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Sponsor information

Organisation

Medicines from Earth LTD

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Sponsor type

Industry

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Funder(s)

Funder type

Industry

Funder Name

Medicines from Earth LTD (Bulgaria)

Results and Publications

Publication and dissemination plan

The study will soon be over and we are ready to publish our preliminary results by next month in an indexed open access medical journal.

Intention to publish date

01/03/2014

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request