ISRCTN11812295 https://doi.org/10.1186/ISRCTN11812295

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

Submission date
24/02/2015

Recruitment status
No longer recruiting

Registration date
26/02/2015

Overall study status
Completed

Last Edited
04/05/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 Caucasion 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?
Dr Dimitrios Karakitsos
jkd97227@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Dimitrios Karakitsos

Contact details
3 Ithakis Street
Pallini
Athens
Greece
15351
0030-6947127965
jkd97227@gmail.com

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 packs. yr ± 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
Athens
Greece
11527

Sponsor information

Organisation
Medicines from Earth LTD

Sponsor details
Saborna 4 Entr B
Sofia
Bulgaria
1000
+30-6944645533
info@medfromearth.com

Sponsor type
Industry

Website
www.medfromearth.com

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