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Zeolite: Investigation of the effectiveness and safety as an oral chelating agent for heavy metals - A comparison between different commercially available preparations

Submission date
25/06/2012

Recruitment status
No longer recruiting

Registration date
10/07/2012

Overall study status
Completed

Last Edited
10/07/2012

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims?
Heavy metal toxicity is a burden on everyone. Toxic buildup causes numerous health issues from cancer to autism and anything in between. Zeolite has been used in the past to remove heavy radioactive metals from land, water and humans. The focus of this study was to prove zeolite is effective at safely removing heavy metals from your body.

Who can participate?
Anyone over the age of 18 was eligible to participate in the study. The only people that were not allowed to participate were those using heavy metal based medications (such as lithium). The participation period is over and there will be no further recruitment for this trial. Participants were asked to stop eating seafood before and during the trial because of the high presence of metals that may interfere with the results.

What does the study involve?
Three different zeolite products were used to see how well each worked. Two liquid products (1 drop and 1 spray) and one powder product were compared. 20 subjects were split to three groups, 10 on the powdered product, 5 on the liquid product and 5 on the spray product. Each participant stayed on the treatment for 6 days to show how effective the products are. Then all of the participants were put on the highest levels of the powdered product for four weeks to confirm the safety of zeolite for human consumption.

What are the possible benefits and risks of participating?
Participants were expected to see lower toxicity levels and experience an overall healthier feeling after taking zeolite. Side effects were not expected, but minor bloating occurred with one patient.

Where is the study run from?
Lipogenex Anti-Aging Center in Scottsdale, Arizona.

When is study starting and how long is it expected to run for?
The study took place from January 2012 through March 2012.

Who is funding the study?
The Zeolite Trial Ethics Committee sponsored the study and was responsible for any costs that were associated with it.

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
N/A

Study information

Scientific Title
Zeolite: A randomized controlled trial to investigate the effectiveness and safety as an oral chelating agent for heavy metals A comparison between different commercially available preparations

Study objectives
This study was performed to evaluate the effectiveness of zeolite as an oral chelating agent for heavy metals. Three different commercially available zeolite preparations for oral consumption were used: a nano-spray, oral drops, and a powdered-form preparation. The chelating capabilities of the different zeolite preparations on 21 different heavy and potentially toxic metals were measured in urinary excretion in 20 human subjects. The excretion rates were

compared to baseline (non-consumption) and to each other. The safety was evaluated with pre and post testing of blood counts, chemistry, as well as liver and kidney function. It was possible to observe the capability of different zeolite preparations to increase the excretion of heavy metals from the human body in a safe manner. The effectiveness of three different zeolite preparations was observed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Zeolite Trial Ethics Committee, 20 December 2011

Study design
Double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Heavy Metal contamination

Interventions
Twenty human subjects were randomly selected and divided into two groups.

Group A (10 subjects) was tested only on the zeolite powder supplement (Zeolite Pure by ZEO Health) and group B was tested first on a different zeolite product (either the Natural Cellular Defense or ACZ Nano extra strength) and last on the powdered form (Zeolite Pure by ZEO Health). All subjects were placed on an all-seafood restricted diet for a week prior to the study and during the time of the study, until they completed all urine measurements for heavy metals. This measure was taken as a control in order to prevent any new contamination that might alter the excretion rates between subjects. All subjects received a complete blood count and comprehensive metabolic panel (blood test) as a baseline assessment prior to onset of the study. This measure was taken to compare results after the consumption of zeolite to assess safety. Each subject received a six hour timed urine collection and analysis for heavy metals as a baseline to assess the levels of metals their body is able to excrete without the help of any chelating agent.

Group A (10 subjects) stayed on one scoop (5 grams) of Zeolite Pure powder (by ZEO Health) for 5 days. One scoop was the lowest recommended dose from the supplement company (ZEO Health). On the morning of the 6th day subjects received one scoop (5 grams) of the powder and

collected all urine for 6 hours. First morning urine was discarded by all subjects. All subjects received 2 liters of bottled water and were asked to consume it within five hours during the urine collection time. A sample of the collected urine was sent for analysis for heavy metal excretion to Genova Diagnostics. Analysis was performed according to Genova Diagnostics standard procedures. The lab (Genova Diagnostics) was blind as to if any and which chelating agent was present in the testing process both at baseline and during zeolite intake.

Group A subjects stayed on the maximum recommended dose of Zeolite Pure powder of three scoops per day (15 grams) for total of four weeks to evaluate the safety of the product at the highest recommended dose. All subjects were told to report any adverse events or symptoms during the time of study. Subjects received a blood test at the end of the four weeks to evaluate any potential impact of zeolite on blood, chemistry, liver and kidney function values. Subjects were not tested for excretion of heavy metals during the higher consumption of 15 grams of Zeolite Pure powder (by ZEO Health).

Group B (10 subjects) were given randomly either the zeolite oral spay (ACZ Nano extra strength by Results RNA) or the zeolite oral drops (Natural Cellular Defense by Waiora). Subjects took the higher recommended dose by the companies for 5 days. Five subjects took 8 sprays three times per day of the ACZ Nano extra Strength (by Results RNA) and five subjects took 10 drops three times per day of the Natural Cellular Defense (by Waiora). On the 6th day, they received the same higher recommended dose of that zeolite supplement and collected all urine for 6 hours. Subjects were given two liters of bottled water and asked to consume it within five hours during the urine collection time. A sample of the collected urine was sent to Genova Diagnostics for analysis for heavy metal excretion. The lab was blind as to if any and which chelating agent was present in the testing process.

After the collection of the urine, subjects in group B received another blood test (complete blood count and comprehensive metabolic panel) to evaluate any impact of the supplement consumed on the liver, kidney function, and blood chemistry (electrolytes). After the blood test was performed subjects were placed on a seven day break from all zeolite so as the body to return to the baseline state of excretion. All subjects in group B continued avoiding all seafood to prevent any recent contamination during the study.

Group B subjects after the seven day break from all zeolite supplements were given the Zeolite Pure powder (by ZEO Health) one scoop (5 grams) per day for 5 days. This was done in order to compare effectiveness of the two products on the same subjects. We wanted to observe if the Zeolite Pure powder had any stronger chelating properties on the same subjects compared to the other two supplements. On the 6th day, while taking the one scoop of powder, a urine collection test was performed as before (six hours timed while drinking two litters of water). Urine samples were analyzed by Genova Diagnostics. All subjects in group B stayed on Zeolite Pure powder higher dose of three scoops (15 grams) for total of four weeks to evaluate the safety of the product. At the end of the four weeks all subjects received a blood test to evaluate any changes in the blood count, chemistry, liver and kidney function. All subjects were asked to report any adverse reactions to all products.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Efficacy - Measures excretion levels of heavy metals for each subject on zeolite preparations compared to their baseline output through urinalysis and blood tests

Secondary outcome measures
Safety and Toxicology - Patients were told to report any adverse reactions. Blood tests pre and post consumption of a single zeolite preparation showed no difference in any of the measured values.

Overall study start date
18/01/2012

Completion date
25/03/2012

Eligibility

Key inclusion criteria
Adults 18 years+

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 subjects

Key exclusion criteria
Subjects on heavy metal based medications

Date of first enrolment
18/01/2012

Date of final enrolment
25/03/2012

Locations

Countries of recruitment
United States of America

Study participating centre
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Sponsor information

Organisation
Zeolite Trial Ethics Committee (USA)

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Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Zeolite Trial Ethics Committee (USA)

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