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INOSIDEX study: to determine whether the combination of inositol and alpha lipoic acid as supplementation of low calories diet can adjust metabolic syndrome parameters in post-menopausal women

Submission date
04/10/2012

Recruitment status
No longer recruiting

Registration date
04/01/2013

Overall study status
Completed

Last Edited
21/10/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Metabolic syndrome is the medical term for a combination of diabetes, high blood pressure and obesity. After the menopause women are often affected by metabolic syndrome and are also at a higher risk of breast cancer. The aim of this study is to determine whether an inositol and alpha lipoic acid supplement and a low-calorie diet can improve metabolic syndrome symptoms in post-menopausal women.

Who can participate?
Post-menopausal women with metabolic syndrome who are at risk of breast cancer (e.g., family history of breast or ovarian cancer)

What does the study involve?
All participants are asked to follow a low-calorie diet and are randomly allocated to take either inositol and alpha lipoic acid or a placebo (dummy) supplement daily for six months. All participants provide blood samples to test their blood levels of sugar, insulin, cholesterol and triglycerides (fats). Height, weight and waist and hip circumference are also measured. After six months more blood samples are taken in order to assess changes in insulin and lipid (fat) levels.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in triglycerides, cholesterol, sugar and insulin levels.

Where is the study run from?
National Cancer Institute of Naples – Fondazione G. Pascale (Italy)

When is the study starting and how long is it expected to run for?
October 2011 to September 2012

Who is funding the study?
National Cancer Institute of Naples and Pharma DANCAN s.r.l. (Italy)

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
02

Study information

Scientific Title
A randomised trial to determine whether the the combination of inositol and alpha lipoic acid as supplementation of low calories diet can adjust metabolic syndrome parameters in post-menopausal women

Acronym
INOSIDEX

Study objectives
It is hypothesised that the inositol improves insulin sensitivity since it works as a second messenger that may achieve an insulin like effect on metabolic enzymes. Inositol combined with

alpha lipoic acid can be used as a dietary supplement in insulin resistant patients in order to increase their insulin sensitiveness. Inositol is a vitamin B complex constituent that rules as second messenger in insulin pathway. Alpha lipoic acid is a fatty acid playing a leading role in the cellular energetic metabolism exerting antioxidant activities on free radicals, promoting glucose cellular intake, taking part in fat catabolism on Krebs cycle. Post-menopausal women are often affected by MS and show the highest incidence of breast cancer in the female population. Breast cancer is also associated with adverse outcomes in patients with metabolic syndrome phenotype.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Cancer Institute of Naples, Scientific and Ethics Committee, 15/09/2011

Study design
Prospective randomized controlled 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Optimum control of insulin resistance and lipid profile in post-menopausal women

Interventions
The study has involved 155 postmenopausal women with metabolic syndrome recruited at visit for clinical-instrumental surveillance program for breast cancer prevention within National Cancer Institute of Naples.

All women were asked to follow a low calorie diet and were assigned randomly to receive daily combination of 4g of inositol and alpha lipoic acid or placebo for six months.

Blood samples and anthropometric measures were taken at baseline and at six months.

Intervention Type
Supplement

Primary outcome measure

1. Reduction of more than 20% of HOMA-IR index and of triglycerides
2. Improvement of high density lipoprotein cholesterol
3. Reduction of anthropometric features such as body mass index, waist and hip ratio
Measured at at baseline and at six months.

Secondary outcome measures
Good control of metabolic syndrome helping diet results with insulin sensitizing supplements

Overall study start date
16/10/2011

Completion date
16/09/2012

Eligibility

Key inclusion criteria
1. Post-menopausal women affected by metabolic syndrome at any age participating to our clinical-instrumental program of surveillance for breast cancer prevention
2. Willing to be assigned to any of the study intervention groups

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
155

Key exclusion criteria
1. Women taking oral hypoglycemic drugs or insulin
2. Women taking statins

Date of first enrolment
16/10/2011

Date of final enrolment
16/09/2012

Locations

Countries of recruitment
Italy

Study participating centre
National Cancer Insitute of Naples
Naples
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Sponsor information

Organisation
Pharma Dancan s.r.l. (Italy)

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Sponsor type
Industry

Funder(s)

Funder type
Government

Funder Name
National Cancer Institute of Naples (Italy)

Funder Name
Pharma Dancan s.r.l. (Italy)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/08/2013		Yes	No