# 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 postmenopausal women

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>	
04/10/2012		Protocol	
Registration date	Overall study status	Statistical analysis plan	
04/01/2013	Completed	[X] Results	
<b>Last Edited</b> 21/10/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	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 postmenopausal 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? Dr Immacolata Capasso icapasso@tiscali.it

# **Contact information**

## Type(s)

Scientific

#### Contact name

Dr Immacolata Capasso

#### Contact details

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# Additional identifiers

Protocol serial number

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 postmenopausal 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

## Study type(s)

Treatment

## 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(s)

- 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.

# Key secondary outcome(s))

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

# 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** 

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

Female

#### 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 Italy 80131

# Sponsor information

## Organisation

Pharma Dancan s.r.l. (Italy)

# Funder(s)

# Funder type

Government

## Funder Name

National Cancer Institute of Naples (Italy)

## Funder Name

Pharma Dancan s.r.l. (Italy)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type	Details	Date created Date	e added Peer reviewed?	Patient-facing?
Results article	results	28/08/2013	Yes	No
Participant information shee	Participant information sheet	11/11/2025 11/1	1/2025 No	Yes