

Italian Society of Endocrinology Prevention Study

Submission date 16/10/2003	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 23/10/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/02/2008	Condition category Nutritional, Metabolic, Endocrine	<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
Not provided at time of registration

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

Acronym

ISEPS

Study objectives

Randomized controlled trial designed to test the hypothesis that an intensive life style intervention is able to prevent the metabolic syndrome in 20-50 years old subjects affected by visceral obesity. Follow-up 5 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Visceral obesity, metabolic syndrome

Interventions

Intervention: Individual intensive counseling to induce life-style change as described in detail in the article: "Validation of a counseling strategy to promote the adoption and the maintenance of physical activity by type 2 diabetic subject by Di Loreto et al (PubMed reference PMID: 12547870)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Prevention of metabolic syndrome

Secondary outcome measures

Reduction of body weight

Reduction of CHD risk

Overall study start date

01/06/2004

Completion date

30/06/2010

Eligibility

Key inclusion criteria

Men and women with visceral obesity

20-50 years old

Waist >88cm (women)

Waist >102cm (men)

Without metabolic syndrome (according to the Adult Treatment Panel III [ATPIII] classification)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

500

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/06/2004

Date of final enrolment

30/06/2010

Locations

Countries of recruitment

Italy

Study participating centre

DIMI

Perugia

Italy

06126

Sponsor information

Organisation

Italian Society of Endocrinology

Sponsor details

c/o Fasi Congress

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Sponsor type

Research organisation

Funder(s)

Funder type

Research organisation

Funder Name

Foundation of Italian Society of Endocrinology

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