

The differential effects of visceral fat reduction compared with subcutaneous fat reduction on parameters of the metabolic indices and adipocytokines

Submission date 18/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/10/2007	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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1

Study information

Scientific Title

Study objectives

The weight reduction with the change of fat distribution influence on the adipokines and metabolic indices.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Institutional Review Board of Yondong Severance Hospital, Yonsei University College of Medicine (South Korea) on the 6th September 2006 (ref: 3-2006-0044).

Study design

A prospective intervention study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Obesity

Interventions

All patients received all three interventions for 16 weeks:

1. The subjects visited an obesity clinic twice per month and restricted their caloric intake to less than their usual intake by 600 kcal/day
2. All patients were encouraged to achieve the goal of five hours of aerobic exercise (physical activity of moderate intensity, such as brisk walking, light jogging or stationary ergometer usage) per week
3. They were also administered 10 - 15 mg of sibutramine (in the morning)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sibutramine

Primary outcome measure

The changes of body fat distribution and adipocytokines, determined by computed tomography scan and measured both before and 16 weeks after the weight reduction program.

Secondary outcome measures

The relationship of body fat distribution and adipocytokines, determined by computed tomography scan and measured both before and 16 weeks after the weight reduction program.

Overall study start date

06/09/2006

Completion date

31/05/2007

Eligibility

Key inclusion criteria

1. Apparently healthy, either sex, aged 18 - 60 years
2. Non-smokers
3. Low alcohol consumers
4. Overweight or obese with an average Body Mass Index (BMI) of 23 kg/m² or greater

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

52

Key exclusion criteria

1. A past history of cardiovascular disease
2. Diabetes
3. Moderate to severe hypertension (resting blood pressure greater than 170/100 mmHg)
4. Renal impairment (serum creatinine greater than 120 µmol/L) or overt proteinuria
5. Obesity caused by an endocrine disorder
6. Psychiatric disorders
7. Current pregnancy or breast-feeding
8. A body weight fluctuation of more than 5 kg in the previous six months
9. Taking any kind of medication

Date of first enrolment

06/09/2006

Date of final enrolment

31/05/2007

Locations

Countries of recruitment

Korea, South

Study participating centre**Department of Family Medicine**

Seoul

Korea, South

135-270

Sponsor information

Organisation

Yonsei University College of Medicine (South Korea)

Sponsor details

250 Sungsan-Ro

Seodaemun-gu

Seoul

Korea, South

120-752

Sponsor type

University/education

Website

<http://medicine.yonsei.ac.kr/en/index.asp>

ROR

<https://ror.org/01wjejq96>

Funder(s)

Funder type

University/education

Funder Name

Yonsei University College of Medicine (South Korea) - faculty research grant (2006)

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