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Development of a new foot-to-foot standing bioelectrical impedance analysis device to measure the abdominal visceral fat

Submission date 25/07/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 26/10/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 31/05/2017	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Bioelectrical impedance analysis (BIA) is a commonly used method for estimating body composition, and in particular body fat. Visceral fat is body fat that is stored within the abdominal cavity around internal organs such as the liver, pancreas and intestines. The aim of this study is to test a newly developed standing -posture BIA system to see whether it can accurately measure abdominal visceral fat.

Who can participate?
Healthy Taiwanese adults with normal physical activity

What does the study involve?
The abdominal visceral fat area measured using BIA is compared with the area measured using an abdominal computerized tomography (CT) scan.

What are the possible benefits and risks of participating?
The risks to participants are exposure to radiation during the CT scan, but this is a safe and legal dose.

Where is the study run from?
Dali Jen-Ai Hospital (China)

When is the study starting and how long is it expected to run for?
January 2008 to December 2013

Who is funding the study?
National Science Council of the Republic of China (China)

Who is the main contact?
Dr Kuen-Chang Hsieh

Contact information

Type(s)
Scientific

Contact name
Dr Kuen-Chang Hsieh

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402

Additional identifiers

Study information

Scientific Title
Using computerized tomography to evaluate the foot-to-foot standing bioelectrical impedance analysis device to measure the abdominal visceral fat area

Study objectives
The newly developed standing-posture bioelectrical impedance analysis (BIA) system with four-contact electrodes can measure abdominal visceral fat area with accuracy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB) of Advisory Committee at Jen-Ai Hospital, 11/05/2010, ref: 99-02

Study design
Randomised study

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Abdominal visceral fat measurement in healthy volunteers

Interventions

1. Abdominal VFA measurements using a standing BIA system
2. Abdominal VFA measurements using abdominal computerized tomography (CT) scanned at the L4-L5 level

Both of these two measurements were performed subsequently at the same condition.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Abdominal VFA measurements obtained using abdominal computerized tomography (CT) scanned at the L4-L5 level

Key secondary outcome(s))
Abdominal VFA measurements obtained using a standing BIA system

Completion date
31/12/2013

Eligibility

Key inclusion criteria
Healthy subjects with normal physical activity were selected in Taiwan

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. The participants had no major diseases, such as diabetes, cancer, kidney dysfunction, liver diseases or long-term asthma
2. Pregnant women or women who were likely to become pregnant, menstruating women
3. Individuals with electronic implants (electronic devices attached to the body)

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Taiwan

Study participating centre
National Chung Hsing University
Taichung 402
Taiwan
402

Sponsor information

Organisation
Charder Electronic Co.Ltd. (Taiwan)

Funder(s)

Funder type
Government

Funder Name
National Science Council of the Republic of China (China) (ref: NSC100-2410-H-028-001-MY3)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration