ISRCTN44356063 https://doi.org/10.1186/ISRCTN44356063

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

| | | |
|---|---|---|
| **Submission date**<br>25/07/2012 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>26/10/2012 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>31/05/2017 | **Condition category**<br>Other | [_] Individual participant data<br>[_] 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

### Contact details
Office of Physical Education and Sport
National Chung Hsing University
250 Kuo Kuang Road
Taichung 402
Taiwan
402

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# 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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Screening

### 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
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 measure
Abdominal VFA measurements obtained using abdominal computerized tomography (CT) scanned at the L4-L5 level

### Secondary outcome measures
Abdominal VFA measurements obtained using a standing BIA system

### Overall study start date
01/01/2008

### Completion date
31/12/2013

## Eligibility

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

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
116 females and 154 males

### 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)

### Sponsor details
No.103 Guozhong Rd
Dali District
Taichung
Taiwan
404

### Sponsor type

Industry

# 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

**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