

# Normalising sex hormone levels in obese hypogonadal men

<b>Submission date</b> 27/08/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 06/09/2010	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<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**  
Prof Frances Hayes

**Contact details**  
UCD Clinical Research Centre  
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Ireland  
4

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
Letrozole2010-1

## Study information

**Scientific Title**

The effects of normalising sex hormone levels in obese hypogonadal men: a prospective randomised comparator controlled parallel arm clinical trial

**Study objectives**

Normalising sex hormone levels decreases inflammation in men with obesity related hypogonadism.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Single centre randomised, comparator controlled, parallel arm, open label clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Obesity, male hypogonadism

**Interventions**

1. Letrozole 2.5 mg tablet (Femara®) once weekly by oral ingestion for 12 weeks (12 tablets, Test Product).
2. Testosterone undecanoate 1 g injection (Nebido®) every 6 weeks by intramuscular administration for 12 weeks (2 injections, Comparator).

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Letrozole (Femara®), Testosterone undecanoate (Nebido®)

**Primary outcome measure**

Change in the serum concentration of the pro-inflammatory cytokine, C-reactive protein, measured after 6 and 12 weeks of drug therapy.

**Secondary outcome measures**

Measured after 12 weeks of drug therapy:

1. The change in the serum concentration of other pro-inflammatory cytokines: interleukin-6 (IL-6), tumour-necrotising factor alpha (TNFa), (interleukin-1-alpha (IL1a), interferon alpha (IFNa)
2. The change in the time taken to walk 500 m at a moderately intense pace
3. The change in erectile function
4. The change in modifiable cardiovascular disease risk factors including blood pressure, glycosylated haemoglobin, insulin resistance (homeostatic model of assessment), lipid fractions and weight
5. The change in quality of life

**Overall study start date**

15/11/2010

**Completion date**

30/09/2012

**Eligibility****Key inclusion criteria**

Men who satisfy all of the following may be included in the study:

1. Age between 18 and 65 years inclusive
2. Body mass index (BMI) greater than 30 kg/m<sup>2</sup>
3. Serum total testosterone concentrations less than 8.0 nmol/L on two consecutive occasions. The blood that will be used for measurement of the testosterone concentrations will be taken from research participants after a 12 hour fast and between the hours of 0800 to 1100.
4. Willingness to voluntarily sign a statement of informed consent to participate in the study

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Target number of participants**

90

**Key exclusion criteria**

Men with any of the following conditions will be excluded from the study:

1. Use of systemic glucocorticoid, sex hormone or anticoagulant therapy, or a medication known

to effect sex hormone bioactivity during the 6 months prior to study entry (i.e., screening visit)

2. Known hypersensitivity to the active substances or any of the excipients of Femara® or Nebido®
3. Hypothalamic pituitary disease
4. Untreated obstructive sleep apnoea syndrome
5. Haemophilia
6. Psychotic mental illness
7. Inability to understand the participant information or to give informed consent
8. History of cancer
9. History of prostatic intra-epithelial neoplasia (PIN)
10. Severe lower urinary tract symptoms (International Prostate Symptom Score greater than 19)
11. Erythrocytosis (haematocrit greater than 0.5, or haemoglobin greater than 17 g/dl)
12. Prostate specific antigen (PSA) level greater than 3 ng/ml
13. Moderate to severe chronic kidney disease (estimated glomerular filtration rate [eGFR] less than 30 ml/min/1.73 m<sup>2</sup>)
14. Severe liver disease (serum alanine transferase level greater than 150 IU/L)
15. Significant cardiomyopathy (left ventricular ejection fraction less than 30%)
16. Greater than 2 seizures during the 12 months prior to study entry
17. Requiring fertility treatment
18. Any clinically significant chronic disease that might, in the opinion of the investigator, interfere with the evaluations or preclude completion of the trial (e.g., severe chronic lung disease, terminal illness)
19. Previous randomisation into this study
20. Concurrent participation in another clinical trial
21. Participation in another clinical trial during the twelve weeks prior to study entry (i.e. screening visit)

**Date of first enrolment**

15/11/2010

**Date of final enrolment**

30/09/2012

## **Locations**

**Countries of recruitment**

Ireland

**Study participating centre**

UCD Clinical Research Centre

Dublin

Ireland

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## **Sponsor information**

**Organisation**

University College Dublin (UCD) (Ireland)

**Sponsor details**

Belfield  
Dublin  
Ireland  
D4

**Sponsor type**

University/education

**Website**

<http://www.ucd.ie/>

**ROR**

<https://ror.org/05m7pjf47>

**Funder(s)****Funder type**

Government

**Funder Name**

Health Research Board (Ireland)

**Alternative Name(s)**

HRB

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Ireland

**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