

Normalising sex hormone levels in obese hypogonadal men

Submission date 27/08/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 06/09/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/09/2010	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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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/m²
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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

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 m²)
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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration