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Normalising sex hormone levels in obese hypogonadal men

Submission date	Recruitment status	[X] Prospectively registered
27/08/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/09/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/09/2010	Nutritional, Metabolic, Endocrine	[ ] 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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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/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

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 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)

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