ISRCTN56557137 https://doi.org/10.1186/ISRCTN56557137

New formulation of testosterone undecanoate in hypogonadal men: a pharmacokinetic and pharmacodynamic study of a novel formulation of testosterone undecanoate in hypogonadal Asian men

Submission date
23/03/2004

Registration date
01/04/2004

Last Edited
10/10/2014

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
WHO/HRP ID A25166

Study information

Scientific Title

Study objectives
1. Describe the Pharmacokinetic (PK) profile of a new formulation of Testosterone Undecanoate (TU) (250 mg/ml in soy bean oil); and
2. Compare two doses of this formulation of TU with a single dose of formulations that are currently being evaluated in clinical trials

Due to funding limitations and focus on an alternative intervention, the study was never initiated and has been withdrawn from the World Health Organization (WHO) directory.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Study participants will be randomised to receive a single administration (injection) of one of the following:
1. 500 mg of the novel TU formulation
2. 1000 mg of the novel TU formulation
3. 1000 mg of 125 mg/ml TU in tea seed oil
4. 1000 mg of 250 mg/ml TU in caster oil.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Testosterone undecanoate

Primary outcome(s)

1. Circulating concentrations of testosterone at 12 weeks
2. Profile of testosterone concentrations over time at 12 weeks
3. Gonadotropin concentrations at 12 weeks

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/01/1999

Reason abandoned (if study stopped)
Due to funding limitations and focus on an alternative intervention, the study was never initiated and has been withdrawn from the directory.

Eligibility

Key inclusion criteria
1. Male participants age 18 to 50 years
2. Diagnosed with hypogonadism (androgen values below the normal range for the centre)
3. Not concurrently undergoing other androgen therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
No exclusion criteria

Date of first enrolment
01/01/1997

Date of final enrolment
01/01/1999

Locations

Countries of recruitment
China

India

Indonesia

Switzerland

Study participating centre
World Health Organization
Geneva
Switzerland
CH-1211

Sponsor information

Organisation
UNDP/UNFPA/WHO/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA) /World Health Organization (WHO)/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

Funder Name
Test compounds donated by manufacturer (Xianju Pharmaceutical Corporation, Zhejiang, People's Republic of China).

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration