

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

Recruitment status

Stopped

☐ Prospectively registered

☐ Protocol

Registration date

01/04/2004

Overall study status

Stopped

☐ Statistical analysis plan

☐ Results

Last Edited

10/10/2014

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Kirsten Vogelsong

Contact details

World Health Organization

20 Avenue Appia

Geneva

Switzerland

CH-1211

vogelsongk@who.int

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Due to funding limitations and focus on an alternative intervention, the study was never initiated and has been withdrawn from the World Health Organization (WHO) directory.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

Primary study design

Interventional

Study design

Randomised controlled trial

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 castor 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Due to funding limitations and focus on an alternative intervention, the study was never initiated and has been withdrawn from the directory.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