

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

<b>Submission date</b> 23/03/2004	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/04/2004	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/10/2014	<b>Condition category</b> 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

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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Due to funding limitations and focus on an alternative intervention, the study was never initiated and has been withdrawn from the World Health Organization (WHO) directory.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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### 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 measure**

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

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/01/1997

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Target number of participants**

72

**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)

**Sponsor details**

World Health Organization

20 Avenue Appia

Geneva

Switzerland

CH-1211

**Sponsor type**

Research organisation

**Website**

<http://www.who.int/reproductive-health/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**

### **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