Testosterone undecanoate combined with depomedroxyprogesterone acetate in two month intervals in Asian men

	Prospectively registered
Stopped	Protocol
Overall study status	Statistical analysis plan
Stopped	Results
Condition category	Individual participant data
Pregnancy and Childbirth	Record updated in last year
	Stopped Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number WHO/HRP ID A15242

Study information

Scientific Title

Study objectives

To assess the efficacy of 500 mg Testosterone Undecanoate (TU) in combination with either 150 or 250 mg Depomedroxyprogesterone Acetate (DMPA) in suppression of sperm production, while maintaining adequate testosterone levels in fertile Asian men.

Due to funding limitations and focus on an alternative intervention, the study was never initiated and has been withdrawn from the World Health Organization (WHO) directory.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

Not Specified

Health condition(s) or problem(s) studied

Male contraception

Interventions

- 1. 500 mg TU and 150 mg DMPA injected at eight week intervals (n = up to 32)
- 2. 500 mg TU and 250 mg DMPA injected at eight week intervals (n = up to 32)

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Testosterone undecanoate (TU), depomedroxyprogesterone acetate (DMPA)

Primary outcome(s)

- 1. Changes in sperm concentrations to azoospermia or severe oligozoospermia at 24 weeks
- 2. Time to suppress spermatogenesis at 24 weeks

Key secondary outcome(s))

Suppression of gonadotropins and maintenance of normal blood testosterone levels at 24 weeks.

Completion date

01/06/2004

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Due to funding limitations and focus on an alternative intervention, the study was never initiated and has been withdrawn from the World Health Organization (WHO) directory.

Eligibility

Key inclusion criteria

- 1. Men in good health, aged 20 to 45
- 2. No desire for children for next 15 months
- 3. Normal reproductive state:
- a. sperm concentrations greater than or equal to 20 million/ml
- b. sperm motility greater than 50% (rapid and slow progressive) or grade a greater than 15%
- c. morphology greater than 15% normal forms using the World Health Organisation (WHO) strict criteria, or
- d. within the normal range for the centre
- 4. Body mass index between 20 and 29 kg/m^2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

No exclusion criteria

Date of first enrolment

01/06/2003

Date of final enrolment

01/06/2004

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

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)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration