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

Submission date 22/03/2004	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/04/2004	**Overall study status** Stopped	
Last Edited 20/08/2008	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

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Due to funding limitations and focus on an alternative intervention, the study was never initiated and has been withdrawn from the World Health Organization (WHO) directory.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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

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

Overall study start date
01/06/2003

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Due to funding limitations and focus on an alternative intervention, the study was never initiated and has been withdrawn from the World Health Organization (WHO) directory.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

Age group
Adult

Sex
Male

Target number of participants
64

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

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)

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