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The effect of Testosterone Undecanoate (TU) alone or combined with Depot Medroxyprogesterone Acetate (DMPA) on sperm production of Indonesian fertile men

Submission date
19/03/2004

Recruitment status
No longer recruiting

Registration date
01/04/2004

Overall study status
Completed

Last Edited
07/08/2008

Condition category
Pregnancy and Childbirth

[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

WHO/HRP ID A05082

Study information

Scientific Title

Study objectives
To assess the efficacy of 500 mg of Testosterone Undecanoate (TU) alone or combined with Depot Medroxyprogesterone Acetate (DMPA) to suppress sperm production in fertile Indonesian men.

Please note that as of 24/09/07 this trial record was updated significantly by the World Health Organization (WHO) Technical Officer. The title was amended from 'Effect of Testosterone Undecanoate (TU) combined with Depomedroxyprogesterone Acetate (DMPA) on sperm production' to the above title, and any other changes to this record will be mentioned under the date 24/09/2007.

Ethics approval required
Old ethics approval format

Ethics approval(s)
As of 24/09/2007 ethics approval received from:
1. National Family Planning Coordinating Board, Indonesia: approval granted 26 November 1997
2. Sriwijaya University, Palembang, Indonesia approval granted 11 June 1998
3. University of Indonesia approval granted 31 August 1998
4. WHO/HRP Scientific and Ethical Review Group approval granted 30 October 1998
5. WHO Secretariat committee for research involving human subjects approval granted 3 November 1999

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Male contraception

Interventions
1. 500 mg TU injections at six week intervals (n = 20)
2. 500 mg TU injections at six week intervals and 300 mg DMPA injections at 12 week intervals (n = 20)

Injections administered for up to 48 weeks; participants followed for recovery in semen parameters for an additional 48 weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Testosterone Undecanoate (TU), Depot Medroxyprogesterone Acetate (DMPA)

Primary outcome measure
1. Azoospermia (no sperm present in ejaculate) or severe oligozoospermia (less than 1 million sperm/mL)
2. Pregnancy
3. Time to suppress spermatogenesis

Follow-up duration for primary endpoints: up to 48 weeks

Secondary outcome measures
Added as of 24/09/2007:
1. Safety
2. Side effects

Overall study start date
01/07/2000

Completion date
01/07/2002

Eligibility

Key inclusion criteria
Current inclusion criteria as of 24/09/2007:
Male participants:
1. Age 21 to 45 years
2. Good general health
3. Blood parameters (peptide hormones, clinical chemistry, haematology, Prostate Specific Antigen [PSA]) in normal range
4. Semen parameters in normal range:
4.1. Sperm concentration 20 million/mL
4.2. Sperm morphology greater than 30% normal

4.3. Sperm 50% forwardly motile
5. Couples must be in a stable relationship, dissatisfied with their current method of contraception and have no history of infertility

Female partners:
1. Age of consent to 35 years
2. Regular menstrual cycles
3. No history of Pelvic Inflammatory Disease (PID) in last 12 months
4. Not pregnant
5. Willing to have physical exam and to participate in trial

Previous inclusion criteria:
Male participants:
1. Age 21 to 45 years
2. Good general health
3. Blood parameters (peptide hormones, clinical chemistry, haematology) in normal range
4. Semen parameters in normal range:
a. sperm concentration 20 million/mL
b. sperm morphology greater than 30% normal
c. sperm 50% forwardly motile

Female partners:
1. Age of consent to 35
2. Regularly cycling
3. No history of Pelvic Inflammatory Disease (PID) in last 12 months
4. Not pregnant
5. Willing to have physical exam and to participate in trial

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
40

Key exclusion criteria
Added 24/09/07:
1. History of active or chronic cardiac, renal, hepatic or prostatic disease or other serious diseases such as diabetes mellitus, hyperlipoproteinemia, etc.
2. Men with active or persistent genitourinary infection
3. Use of medication such as sex steroids or barbiturate
4. Couples in which the wife is breastfeeding

Date of first enrolment
01/07/2000

Date of final enrolment
01/07/2002

Locations

Countries of recruitment
Indonesia

Switzerland

Study participating centre
World Health Organization
Geneva-27
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-27
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