

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	<input type="checkbox"/> Prospectively registered
Registration date 01/04/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/08/2008	Condition category Pregnancy and Childbirth	<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

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Added as of 24/09/2007:

1. Safety
2. Side effects

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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)

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