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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
19/03/2004	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
01/04/2004	Completed	Results
Last Edited	Condition category	Individual participant data
07/08/2008	Pregnancy and Childbirth	<ul><li>Record updated in last year</li></ul>

#### 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 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

#### 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