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Assessing acceptability and sexual behaviour during male contraception: mood, behavior and user's perspectives related to sperm suppression with norethisterone enanthate (NET-EN) plus testosterone undecanoate (TU) in normal men

Submission date 19/03/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/04/2004	**Overall study status** Completed	
Last Edited 10/10/2014	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Kirsten Vogelsong

Contact details
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211
vogelsongk@who.int

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WHO/HRP ID A05104

Study information

Scientific Title

Study objectives
1. To pilot test instruments to measure mood, sexual function and behavior of men from the general population and men participating in a trial of a hormonal contraceptive
2. To pilot instruments that evaluate the acceptability of a male hormonal method of contraception in its developmental states
3.To collect preliminary data regarding the acceptability of the hormonal regimens under investigation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by:
1. Tthe Ethics Committee of the University of Bologna, 23/06/2000
2. HRP Scientific and Ethical Review Group, 05/09/2000
3. WHO's Secretariat Committee on Research Involving Human Subjects, 13/11/2000

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
Pre-treatment control period for 4-6 weeks; then treatment for 48 weeks; and a post-treatment recovery period of at least 18 weeks. Treatment groups are:

Group 1: Net-En 200 mg/six weeks plus TU 1000 mg/six weeks for 12 weeks followed by Net-En 200 mg/12 weeks plus TU 1000 mg/12 weeks for 36 weeks (n = 10)
Group 2: Net-En 200 mg/six weeks plus TU 1000 mg/six weeks for 12 weeks followed by placebo /12 weeks + TU 1000 mg/12 weeks for 36 weeks (n = 10)
Group 3: Net-En 200 mg/eight weeks plus TU 1000 mg/eight weeks for 48 weeks (n = 10)
Group 4: Net-En 200 mg/12 weeks plus TU 1000 mg/12 weeks for 48 weeks (n = 10)
Group 5: Placebo/six weeks for 12 weeks followed by placebo/12 weeks for 36 weeks (n = 10)
Group 6: Untreated controls (n = 40)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Norethisterone enanthate, testosterone undecanoate

Primary outcome measure
Current primary outcome measures as of 10/09/2007:
1. Attitudes towards contraception
2. Motivation to participate in the clinical trial
3. Reactions to the various treatment regimens
4. Overall assessment of the method
5. Reports of physical status, mood, sexual function and behaviour

Previous primary outcome measures:
1. Socio-demographic and economic profile of study participants
2. Motivating factors for participation in the trial
3. Contraceptive history of participant and partner
4. Side effects experienced during the study
5. Measurements of sexual function
6. Measurements of aggression, irritability, and other mood states
7. Measurement of user's perspectives and acceptability

Follow-up duration for primary endpoints: 72 - 74 weeks, including control (baseline) period.

Secondary outcome measures
1. Background characteristics of participants
2. Contraceptive history
3. Reports of partners' reactions

Overall study start date
01/07/2000

Completion date
01/12/2002

Eligibility

Key inclusion criteria
Current inclusion criteria as of 10/09/2007:
Male participants were recruited according the the recruitment strategy, inclusion criteria and exclusion criteria outlined on page 13 of clinical protocol number 303923 "NET-EN plus TU for male contraception" The World Health Organization did not support the clinical trial, but sponsored this acceptability component.

Previous inclusion criteria:
Same as those for the protocol for the clinical evaluation of the safety and efficacy of the hormonal regimens. The clinical component is supported by the private sector and supported by the World Health Organization (WHO) Department of Reproductive Health and Research; therefore, we do not have access to the protocol.

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
90

Key exclusion criteria
Male participants were recruited according to the recruitment strategy, inclusion criteria and exclusion criteria outlined on page 13 of clinical protocol number 303923 "NET-EN plus TU for male contraception" The World Health Organization did not support the clinical trial, but sponsored this acceptability component.

Date of first enrolment
01/07/2000

Date of final enrolment
01/12/2002

Locations

Countries of recruitment
Italy

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), and other sources

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2006		Yes	No