

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 ☒ 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

Protocol serial number
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. The 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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

Completion date

01/12/2002

Eligibility**Key inclusion criteria**

Current inclusion criteria as of 10/09/2007:

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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)

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

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