Version 1.0
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UHealth UNIVERSITY OF MIAMI HEALTH SYSTEM | UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

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Patient Satisfaction After Switching to Oral Testosterone Undecanoate in Men Currently on Testosterone Therapy

PRINCIPAL INVESTIGATOR

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SPONSOR:

Clarus Therapeutics
Northbrook, IL

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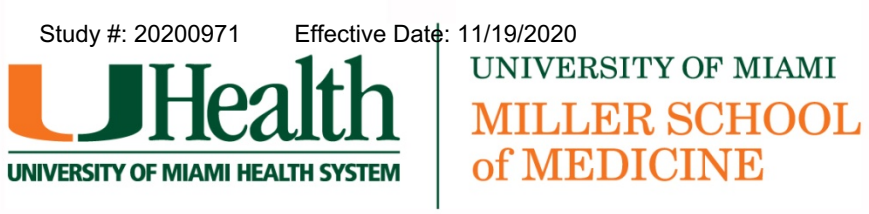

Investigator's Statement

This clinical trial shall be conducted in compliance with the protocol, as referenced herein, and all applicable local, national, and international regulatory requirements to include, but not be limited to:

- International Conference on Harmonization (ICH) Guidelines on Good Clinical Practice (GCP)
- Ethical principles that have their origins in the Declaration of Helsinki
- Food and Drug Administration (FDA) Code of Federal Regulation (CFR):
  - Title 21CFR Part 50 and 45 CFR Part 46, Protection of Human Patients
  - Title 21CFR Part 54, Financial Disclosure by Clinical Investigators
  - Title 21CFR Part 56, Institutional Review Boards
  - Title 45 CFR Parts 160, 162, and 164, Health Insurance Portability and Accountability Act (HIPAA)

As the Principal Investigator, I understand that my signature on the protocol constitutes my agreement and understanding of PI responsibilities to conduct the clinical trial in accordance to the protocol and applicable regulations. Furthermore, it constitutes my understanding and agreement that any changes initiated by myself, without prior agreement in writing from the Sponsor, shall be defined as a deviation from the protocol, and shall be formally documented as such.

I understand that my signature constitutes agreement and understanding of acceptance of the defined responsibilities of a Sponsor-Investigator as defined by the protocol, applicable FDA Regulations, and/or business contracts, but does not in any capacity relieve me of my responsibilities as the Sponsor-Investigator. Additionally, my signature constitutes my understanding and agreement that any changes to the protocol shall be implemented timely with my review and approval prior to implementation.

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INVESTIGATOR'S AGREEMENT

I confirm that I have read this protocol, I understand it, and I will work according to this protocol and to the ethical principles stated in the latest version of the Declaration of Helsinki, the applicable ICH guidelines for good clinical practices, and the applicable federal, state, and local laws, rules, and regulations relating to the conduct of the protocol.

I have read and understand the information in the Instructions for Use (and/or other such pertinent safety information) regarding the risks and potential benefits.

I agree to inform all those who assist/collaborate with me in the conduct of this study of their responsibilities and obligations.

Once the protocol has been reviewed and approved by the Institutional Review Board (IRB) I understand that any change(s) made during the course of the study must also (first) be approved by the IRB prior to implementation, except when such modification is made to remove any immediate hazard(s) to the subject(s).

I certify that I and the study staff responsible, have received the requisite training to conduct this research protocol.

I agree to maintain adequate and accurate records in accordance with the University of Miami policies, federal, state and local laws and regulations.

I agree to maintain the confidentiality of all information received and/or developed in connection with this protocol.

Ranjith Ramasamy

Print Name of Physician

Physician's Signature

7/20/20

Date

1. BACKGROUND

1.1 Study Disease

Testosterone is an anabolic steroid and the primary male sex hormone promoting development of male reproductive tissues such as prostate and testis. It can activate androgen receptors in its unchanged form or it can be converted to 5α-dihydrotestosterone (DHT) by the enzyme 5-α reductase before binding to the androgen receptor. Once bound, the receptor-hormone complex moves into the cell nucleus altering specific gene sequences on the cellular DNA and modifying transcription. Through these actions, it promotes protein synthesis and thus growth of tissues that are sensible to its action (1).

Testosterone deficiency is defined by an insufficient production of normal amounts of testosterone due to a failure of the testicles or pituitary gland. It affects more than 10% of men worldwide (2) and occurs in association with aging, chronic disease, or other modifiable risk factors such as obesity and diabetes (1). Testosterone deficiencies have been associated with decreased muscle mass (3), lower bone mineral density (4), lower hematocrit and hemoglobin concentrations (5), and diminished energy and sexual function compared to normal men (6, 7).

1.2 Study Interventions

Administration of exogenous testosterone as an efficacious treatment for male testosterone deficiency has been part of medical practice for more than 50 years. Furthermore, testosterone therapy is becoming more widely available and has seen a greater than three-fold increase in use men 40 years and older (8). Among the many benefits, testosterone therapy has been shown to improve bone mineral density, energy, and sexual function (7).

Current delivery systems for testosterone include transdermal gels, patches, injection therapy, long acting subcutaneous pellets, and intranasal gels (9). Oral formulations of testosterone are convenient, easy to use, and avoid the problems of other forms of TRT such as painful injections and transference to women and children, yet have long been unavailable in the United States. Early attempts at oral testosterone development involved methylation, however, methyltestosterone was associated with significant hepatotoxicity (9, 10). Subsequent attempts involved fatty-acid esterification which bypass first pass portal metabolism by way of intestinal lymphatic absorption (testosterone undecanoate). Although testosterone undecanoate avoided hepatotoxicity, absorption was highly dependent on fat consumption and lead to variable responses (11-14).

Jatenzo® is a novel formulation of oral testosterone undecanoate that provides a uniform response, independent of the lipid content in a meal, through a unique self-emulsifying drug delivery system. A phase 3 randomized controlled trial recently demonstrated that Jatenzo® was safely able to restore patients with low testosterone to eugonadal levels (15). Since its approval in 2019, Jatenzo® is the only FDA approved oral testosterone replacement option available in the United States.

1.3 Study Rationale

With a favorable side effect profile and established efficacy, Jatenzo® offers patients another option for testosterone therapy. Advantages of Jatenzo® over more commonly utilized options include ease of delivery, no risk of secondary transference, and avoiding painful injections. Despite these advantages, patient satisfaction with Jatenzo® over other forms of testosterone therapy has not been investigated. Our hypothesis is that Jatenzo® will not lower patient satisfaction in comparison to more commonly used forms of testosterone.

2. HYPOTHESIS

Jatenzo® will not have lower patient satisfaction compared to other forms of testosterone therapy.

3. OBJECTIVES

3.1 Primary Efficacy Objective

Primary outcomes include changes in patient satisfaction measured by TSQM-9 (Treatment Satisfaction Questionnaire for Medication) and changes in hypogonadal symptoms measured by qADAM questionnaire from baseline and at 3 and 6 months.

3.2 Secondary Efficacy Objective

Secondary outcomes will be patient treatment preference compared to prior testosterone therapy at 6 months as well as changes in serum testosterone, estrogen, hematocrit, and PSA from baseline at 3 and 6 months.

4. STUDY DESIGN

4.1 Accrual goal

A total of 40 patients with a diagnosis of testosterone deficiency (testosterone <300 on two consecutive samples collected at least 2 weeks apart off all testosterone therapy) who are currently well controlled on testosterone therapy meeting the eligibility criteria will be recruited from the Department of Urology clinic.

4.2 Duration of Study Participation

Total study duration will be 6 months and subjects will be provided with Jatenzo® for the duration of the study (26 weeks treatment course).

5. STUDY ENTRY, ENROLLMENT AND WITHDRAWAL

5.1 Study Entry

Study entry, as used in this protocol, will be defined as a subject signing informed consent. Study enrollment, as used in this protocol, will be defined as the investigator's confirmation of the subject's eligibility by signing an eligibility checklist. As per University of Miami policy, each study participant, including participants who have failed screening, who sign an informed consent form, should be entered into the study database.

5.2 Enrollment Procedure

Completed and signed protocol-specific eligibility checklist;

All pages of the original signed informed consent forms (ICFs), including HIPAA Form B;
Relevant source documents or medical records such as: subject medical history and physical exam, admission or discharge notes, diagnostic reports, pathologic confirmation of diagnosis, and relevant subject-specific written communication.

Documentation from the Investigator that he/she has determined the subject meets eligibility criteria.

5.3 Cancellation Guidelines

The following are reasons for withdrawal of subjects from the study:

- A subject does not meet the eligibility criteria; (the subject will be considered a screen failure).
- A subject withdraws consent.
- A subject dies during protocol participation from causes other than the study treatment (not due to adverse events).
- A study investigator decides the subject should be withdrawn from the study (e.g. subject non-compliance).

Regardless of reason for withdrawal, an intention to treat analysis will be performed.

All subjects who either fails screening, withdraws from the study, or completes all visits should be de-enrolled from the research database within 48 hours.

6. PATIENT SELECTION/ELIGIBILITY CRITERIA

6.1 Inclusion (Eligibility) Criteria

Subjects must meet the following criteria:

1. Voluntarily sign and date the study consent form(s) which have been approved by an Institutional Review Board (IRB). Written consent must be obtained prior to the initiation of any study procedures.

2. Males between 18 and 65 years of age.

3. Documented diagnosis of testosterone deficiency.

4. Prior treatment with testosterone therapy at the time of enrollment with adequate control of low testosterone symptoms. Serum total testosterone < 300 ng/dL on 2 measurements prior to the initiation of testosterone therapy. Patients must have completed an adequate washout period following prior testosterone therapy (4 weeks for gels and injection based therapies and 16 weeks for subcutaneous pellets).

5. Judged to be in good general health as determined by the principal investigator based upon the results of a medical history, physical examination, vital signs, laboratory profile and a 12-lead electrocardiogram (ECG).

6.2 Exclusion (Eligibility) Criteria

Subjects meeting any of the following criteria will be excluded from the study:

1. History of significant sensitivity or allergy to androgens or product excipients.

2. Clinically significant findings in the pre-study examinations including abnormal breast examination requiring follow-up or abnormal ECG.

3. Abnormal prostate digital rectal examination (DRE) with palpable nodule(s) or I-PSS score > 19 points.

4. Body mass index (BMI) ≥ 40 kg/m2.

5. Clinically significant abnormal laboratory value, in the opinion of the investigator, in serum chemistry, hematology, or urinalysis including but not limited to:

   a. Baseline hemoglobin > 16 g/dL

   b. Hematocrit < 35% or > 50%

6. Poorly controlled blood pressure as defined by SBP >150 or DPB > 90 on two separate measurements

7. Concurrent use of any prohibited medications that can affect testosterone levels or metabolism.

8. History of seizures or convulsions, including febrile, alcohol or drug withdrawal seizures.

9. History of any clinically significant illness, infection, or surgical procedure within 4 weeks prior to study drug administration.

10. History of stroke or myocardial infarction within the past 5 years.

11. History of, or current or suspected, prostate or breast cancer.

12. History of, or current or suspected, pituitary abnormality.

13. History of diagnosed, severe, untreated, obstructive sleep apnea.

14. History of abuse of alcohol or any drug substance in the opinion of the investigator within the previous 2 years.

15. Receipt of any investigational product within 4 weeks or within 5 half-lives prior to the start of treatment.

16. Inability to understand and provide written informed consent for the study.

17. Considered by the investigator or the sponsor-designated physician, for any reason, that the subject is an unsuitable candidate to receive Jatenzo®.

6.3 Study Population

The study will consist of 40 males with a diagnosis of testosterone deficiency with symptomatic control on testosterone therapy.

6.4 Setting

Subjects will be identified from patients visiting the University of Miami – Department of Urology and the UHealth Fertility Center who have received the diagnosis of testosterone deficiency. If they meet the inclusion criteria, the patients will receive an explanation of the study. Patients will be informed both verbally and in written form of the study and procedures involved. The PI, Resident, Fellows and/or the study coordinator will obtain a signed/dated Informed Consent

Document (ICD) before enrolling each subject. Subsequent visits will take place in the same Clinic. Study data will be safely stored in a RedCap database.

7. STUDY DESIGN, CLINICAL, RADIOLOGICAL, LABORATORY AND SURGICAL EVALUATIONS

7.1 Study Design

This is a prospective, single center, open label, single arm clinical study aimed to evaluate patient satisfaction with Jatenzo® for patients with testosterone deficiency in comparison to treatment with other forms of testosterone therapy. Subjects will be enrolled in the study based on selection criteria designed to represent the general population of men with low testosterone while minimizing risk to study participants. Approximately 40 subjects will be enrolled to meet scientific and regulatory objectives. After meeting the selection criteria, the subjects will stop their current testosterone therapy, undergo a washout period, and start Jatenzo® (237mg twice daily with food). Subjects will be followed for 6 months.

7.2 Screening Evaluations and Procedures

The first visit for the patients will be for screening and medical evaluation. Patient's medical history will be collected and documented, and a physical examination will be performed with vital signs.

Previous blood test results will be reviewed including a general chemistry panel and testosterone levels during chart review.

Patients will sign an informed consent and if they meet all inclusion criteria (and do not meet any exclusion criteria), they will be recruited to the study.

7.3 Pre-Treatment Procedures and Evaluations

The results of all screening evaluations must be within clinically acceptable limits, reviewed and approved by the investigator, prior to the start of treatment. Subjects who meet the inclusion criteria and do not meet any of the exclusion criteria will be recruited to the study. While on their current testosterone therapy, patients will have a baseline evaluation of medication satisfaction measured by TSQM-9 (Treatment Satisfaction Questionnaire for Medication) and low testosterone symptoms measured by qADAM questionnaire. They will also have baseline testing of serum testosterone, estrogen, hematocrit, and PSA.

7.4 Treatment procedures

Patient's will stop their current testosterone therapy and undergo a washout period (4 weeks following their last gel or injection based therapy and 16 weeks following their subcutaneous pellet insertion). Once the washout period is completed, they will start Jatenzo® (oral testosterone undecanoate) as 237mg twice daily with food (morning and evening). At the 3 month follow up visit, testosterone will be checked (6 hours after taking Jatenzo®) and testosterone dosage will be titrated per FDA prescribing guidelines (16).

7.5 Follow-Up Procedures and Evaluations:

Follow-up visits will be conducted at 3 and 6 months. These visits shall include:

- Measuring TSQM-9 and qADAM scores of patients at the clinic.
- Taking serum testosterone, estrogen, hematocrit, and PSA.
- Vital signs and physical exam. Blood pressure will also be assessed at week 4 (approximately 3 weeks after starting Jatenzo®). For new onset or exacerbation of pre-existing hypertension, patients will be referred to their primary care physician for treatment. If a dose titration occurs after the 3 month visit, patient will return roughly 3 weeks after for blood pressure check (visit 4).
- Reporting and recording adverse events.

Patient testosterone replacement therapy preference will also be assessed at 6 months.

7.6Reimbursement

The subjects prior to enrollment in the trial will be billed to the insurance or self-pay. Once enrolled in the trial, the medications and the visits will be covered as part of the study. Subjects will be provided testosterone study medication, oral testosterone undecanoate, free of charge. For transportation and parking for the study visits, the subjects will be provided a gift card for $50 at the end of the study.

7.7 Drug/Device

1. Where will the study drug(s) be stored:

Professional Art Center building
1150 NW 14th St , suite 309. Miami, Florida 33136
Andrology Laboratory

2. Describe accountability procedures as they relate to drugs:

   A tracking spreadsheet including: medication serial, date received , date dispensed, ICF date, subject initials and signature; will be located at 1150nw 14th st suite 309 (andrology lab). Miami, FL 33136

3. State who will interact with the sponsor (drugs) for acquisition of investigational product(s):

   Manuel Molina, MD; Clinical coordinator for the clinical trial will be the person interacting with sponsor for acquisition of study drug.

8. ADVERSE EVENTS

8.1 Expected Adverse Events

A phase 3, randomized, active-controlled, open-label study of the efficacy of Jatenzo® in men with low testosterone demonstrated that the most commonly reported adverse reactions (>2% of patients) included headache, hematocrit increase, upper respiratory tract infection, hypertension, high-density lipoprotein decrease, and nausea (15).

8.2 Serious Adverse Events

Serious injury or death

Any adverse event and eventual complication must be recorded at any time during the treatments and follow up visits, and throughout the entire study duration. Patients will be instructed to alert the study investigator by telephone of any side effects occurring in the period after the treatment and until the study end.

For Reporting of adverse events see section 9.

9. DATA AND SAFETY MONITORING PLAN

The study investigators will report to a surgeon monitor Dr. Satyanarayana Ramgopal in the Department of Urology (who is not involved in the study) to ensure data quality and subject safety. The investigators will conduct continuous reviews of the data and subject safety, keeping track of the number of subjects, significant toxicities in accordance with the protocol and observed responses, which will be discussed at research committee meetings. All grade 3-5 adverse events (CTCAE v4.0), regardless of association with oral testosterone, will be entered into study database and reviewed at research committee meetings. In addition, all adverse reactions considered

"serious" will be entered into research database and reviewed by the Surgeon monitor on an ongoing basis. If a death occurs within 30 days of treatment and is determined to be related to the study, the investigators will notify the Department Chair Dr. Dipen Parekh within 1 business day. If an increase in the frequency of grade 3 or 4 adverse events is noted in the study, a report will be submitted to the Department Chair Dr. Dipen Parekh at the time the increased rate is identified. If at any time the principal investigator stops enrollment or stops the study due to safety issues, the Department Chair (Dr. Dipen Parekh) will be notified within 1 business day and a formal letter will be sent to the Department Chair (Dr. Dipen Parekh) to be received within 10 business days. In addition to reporting to the Department chair, all serious events will also be reported to the supervising IRB in the same timely manner.

10. STATISTICAL CONSIDERATIONS

10.1 Primary Study Endpoints

The primary endpoints will be change in patient satisfaction measured by TSQM-9 (Treatment Satisfaction Questionnaire for Medication) and change in low testosterone symptoms measured by qADAM questionnaire after 3 and 6 months of treatment with Jatenzo®.

10.2 Secondary Study Endpoints

The secondary endpoints will be patient treatment preference compared to prior testosterone therapy as well as changes in Testosterone, Estrogen, Hematocrit, and PSA after 3 and 6 months of treatment with Jatenzo®.

10.3 Endpoint definitions

Patient satisfaction and low testosterone symptoms will be measured by TSQM version 9 (Treatment Satisfaction Questionnaire for Medication) and the qADAM questionnaire, respectively.

Patient treatment preference will be evaluated with a questionnaire gauging interest in continuing Jatenzo® versus prior testosterone therapy.

Total testosterone will be expressed in ng/dL, hematocrit (%), estrogen (pg/ml), and PSA ng/ml. Hormone determinations will be done by peripheral venous puncture blood draw.

10.4 Sample size, accrual and study duration

TOTAL SAMPLE SIZE: 40
TOTAL ACCRUAL: 40
ACCURAL DURATION: 1 year

STUDY DURATION: 6 months

10.5 Statistical Analysis and Power calculation

Analyses will be performed on the complete study population using SAS. Statistical testing will be performed at the two-sided 0.05 significance level unless specified. Statistical significance of TSQM-9 and qADAM results will be determined using paired t-tests (two-sided) or Wilcoxon matched pairs signed-rank tests (two-sided). Shapiro-Wilk normality test will be used to determine which test was appropriate. Change in Testosterone, Hematocrit, estrogen and PSA will be analyzed using the ANOVA and MANOVA.

11. INVESTIGATORS RESPONSIBILITIES

11.1 Investigator Responsibility/Performance

The investigator (or a person designated by the investigator) should inform the patient of all pertinent aspects of the study, including the written information.

The investigator should provide the patient ample time and opportunity to inquire about details of the study and to decide whether or not to participate in the study. All questions about the study should be answered to the satisfaction of the patient. Neither the investigator nor the study staff should coerce or unduly influence a patient to participate or to continue to participate in a study.

11.2 Confidentiality

The identity of the patients in this study will be treated as confidential. Patients eligible to participate in the study following the pre-treatment visit will be assigned a unique patient code. The results of the study, including any other data, may be published for scientific purposes but will not give the patients' name or include any identifiable references to them.

However, any records or data obtained as a result of the patient participation in this study may be inspected by the sponsor, by any relevant governmental agency, by the Hospital Ethics Committee, or by the persons conducting this study, provided that such inspectors are legally obligated to protect any identifiable information from public disclosure, except where disclosure is otherwise required by law or a court of competent jurisdiction. These records will be kept private in so far as permitted by law.

11.3 Informed Consent and Permission to Use Protected Health Information

It is the responsibility of the investigator to obtain written informed consent from each subject participating in this study after adequate explanation, in lay language, of the methods, objectives, anticipated benefits, and potential hazards of the study. The investigator must also explain that the subject is completely free to refuse to enter the study or to discontinue participation at any time

(for any reason) and receive alternative conventional therapy as indicated. Prior to study participation, each subject will sign an IRB approved informed consent form and receive a copy of same (and information leaflet, if appropriate).

The investigator or designee **must** explain to the subject before enrollment into the study that for evaluation of study results, the subject's protected health information obtained during the study may be shared with the study sponsor, regulatory agencies, and the IRB. It is the investigator's (or designee's) responsibility to obtain permission to use protected health information per HIPAA from each subject, or if appropriate, the subjects' parent or legal guardian.

11.4 Source Documentation and Investigator Files

The investigator will maintain adequate and accurate records to document the conduct of the study and to ensure that study data can be subsequently verified. These documents will be classified into two separate categories: (1) investigator study file and (2) subject clinical source documents that corroborate data collected on the CRF's. Subject clinical source documents would include hospital/clinic patient records, physician and nurse notes, original laboratory, radiology, pathology, and special assessment reports, QOL forms, and signed informed consent forms. When the CRF or any form is used as the source document, this will be clearly stated in the investigator study file.

At a minimum, the following be documented in source documents:

- Medical history/physical condition and diagnosis of the subject before involvement in the study sufficient to verify protocol entry criteria.
- Study number, assigned subject number, and verification that written informed consent was obtained (each recorded in dated and signed notes on the day of entry into the study)
- Progress notes for each subject visit.
- Laboratory test results.
- Condition and response of subject upon completion of or early termination from the study.

11.5 Recording and Processing of Data

Data for this study will be entered into electronic CRFs in research database (a web-based clinical research management application). A CRF is required for every patient who received any study intervention. The investigator will ensure that the CRF's are accurate, complete, legible and timely. Separate source records are required to support all CRF entries. All corrections to study data will be made by drawing a single line through the information to be corrected without obscuring it. All corrections will be initialed, dated and explained, if necessary. **Do not use "white-out" or obscuring correction tape.**

11.6 Non-Protocol Research

No investigative procedures other than those described in this protocol will be undertaken on the enrolled subjects without the agreement of the IRB.

11.7 Ethics

The investigator agrees to conduct the study in compliance with the protocol, current good clinical practices, and all applicable (local, FDA) regulatory guidelines and standard of ethics

11.8 Essential Documents for the conduct of a clinical trial

Essential documents are those documents with individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced.

The following documents will be on file:

- CV's and license of all investigators.
- IRB documentation/correspondence.
- Documentation of IRB certification.

12. STUDY CALENDAR

Visit # (Time) / Activity	Visit 1 (Week 1) Screening	Visit 2 (Week 4)	Visit 3 (Week 14)	Visit 4 (week 17) If needed	Visit 5 (Week 27)
Medical & Urological History & Questionnaires (TSQM-9 and qADAM)	•		•		•

Visit # (Time) / Activity	Visit 1 (Week 1) Screening	Visit 2 (Week 4)	Visit 3 (Week 14)	Visit 4 (week 17) If needed	Visit 5 (Week 27)
Physical Examination	●	● (BP Only)	●	● (BP Only)	●
Informed Consent	●				
Inclusion & Exclusion Criteria	●				
Blood Analysis (T, E, PSA, HCT)	●		●		●
Drug Dispensing	●		●		
Dose Titration			●		

- Medications will be provided by sponsor

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14. Appendix A

14.1 TSQM-9 Questionnaire

14.2 qADAM Questionnaire

Questions Used as Part of the qADAM Questionnaire

1. How would you rate your libido (sex drive)?
1(terrible) 2(poor) 3(average) 4(good) 5(excellent)

2. How would you rate your energy level?
1(terrible) 2(poor) 3(average) 4(good) 5(excellent)

3. How would you rate your strength/endurance?
1(terrible) 2(poor) 3(average) 4(good) 5(excellent)

4. How would you rate your enjoyment of life?
1(terrible) 2(poor) 3(average) 4(good) 5(excellent)

5. How would you rate your happiness level?
1(terrible) 2(poor) 3(average) 4(good) 5(excellent)

6. How strong are your erections?
(1= extremely weak 5= extremely strong)
1 2 3 4 5

7. How would you rate your work performance over the past 4 weeks?
1(terrible) 2(poor) 3(average) 4(good) 5(excellent)

8. How often do you fall asleep after dinner?
1(never) 2(1-2/week) 3(3-4/week) 4(5-6/week) 5(every night)

9. How would you rate your sports ability over the past 4 weeks?
1(terrible) 2(poor) 3(average) 4(good) 5(excellent)

10. How much height have you lost?
1(2" or more) 2(1.5-1.9") 3(1-1.4") 4(0.5-0.9") 5(none-0.4")

Mohamed et al. (17)

14.3 Patient Preference Questionnaire

1. I plan on continuing to take Jatenzo®.
2. I am undecided if I will continue Jatenzo®.
3. I do not plan on continuing Jatenzo®.