CLINICAL STUDY DOCUMENT

STUDY PROTOCOL

Official Title: An Open-Label Study on the Efficacy of a New Natural Origin Product (FPT-20) in Improving Spermatogenesis and Semen Parameters in Men With Spermatogenic Failure.

Protocol ID: FPT-20-2022

NCT Number: NCT05399212

Document Date: February 6, 2026

1. STUDY BACKGROUND & RATIONALE: This clinical study aims to evaluate the therapeutic efficacy and safety of a novel, naturally derived formulation (FPT-20) rich in targeted flavonoids for supporting spermatogenesis. The biological investigation focuses on the formulation's potential to reduce localized inflammatory processes and support tissue regeneration within the testicular lobules, seminiferous tubule epithelium, and surrounding connective tissues. Additionally, the study assesses its ability to restore Leydig and Sertoli cell functions in patients with spermatogenic failure secondary to chronic testicular inflammation (orchitis).

2. STUDY DESIGN & METHODOLOGY

Study Type: Interventional

Primary Purpose: Treatment

Phase: Phase 4 / Post-Marketing Evaluation

Interventional Study Model: Single Group Assignment (Single-Arm)

Number of Arms: 1

Masking: None (Open-Label)

Allocation: Not Applicable (N/A)

Estimated Enrollment: 16 participants

3. ELIGIBILITY CRITERIA

- Age Limits: Minimum Age: 25 Years | Maximum Age: 40 Years

- Sex/Gender: Male Only (Gender-Based: Yes - Carries the sex chromosome gene XY)

- Accepts Healthy Volunteers: No

3.1. Inclusion Criteria:

1. Adult males aged 25 to 40 years with a confirmed diagnosis of spermatogenesis disorder, oligospermia, asthenozoospermia, or azoospermia that do not meet the standard fertile criteria in terms of sperm quantity and quality.

2. Clinical or ultrasonographic evidence of chronic orchitis or testicular inflammation.

3. Patients with stable, controlled comorbidities (e.g., metabolic diseases, stable HIV/AIDS, HBV, HCV, and tuberculosis) may be included under the investigator's clinical discretion.

3.2. Exclusion Criteria:

1. Patients diagnosed with advanced, metastatic, or terminal cancer.

2. Known hypersensitivity or severe allergic reactions to any of the active components or flavonoids in the FPT-20 formulation.

3. Concomitant use of hormone replacement therapy (HRT) or systemic immunosuppressive drugs during the study period.

4. ARMS AND INTERVENTIONS DESCRIPTION

***Arm Title:** Experimental: FPT-20 Intervention Group

***Arm Description:** A single-arm group consisting of 16 infertile men with spermatogenic failure secondary to testicular inflammation. All participants receive a standardized therapeutic dose of the natural-derived formulation FPT-20.

***Intervention Type:** Drug (Natural Product)

***Intervention Name:** FPT-20

***Intervention Description:** Participants receive FPT-20 orally at a standardized dosage of 1 tablet once daily. The intervention is administered continuously for a duration of 6 to 12 months to ensure sufficient biological exposure for the evaluation of therapeutic efficacy on spermatogenesis.

5. OUTCOME MEASURES

Primary Outcome Measure: Change from Baseline in Progressively Motile Sperm Count.

Description: Total number of progressively motile sperm per ejaculate will be measured via standardized semen analysis to evaluate the therapeutic efficacy of FPT-20.

Time Frame: Baseline, Month 6 (180 days), and Month 12 (360 days).

Secondary Outcome Measures:

1. Serum Hormone Levels: Change from baseline in Testosterone, LH, and FSH levels to assess Leydig and Sertoli cell functional recovery. (Time Frame: Baseline and Month 12).

2. Reduction in Testicular Inflammation: Assessment of inflammatory changes using testicular color Doppler ultrasound. (Time Frame: Baseline and Month 12).

3. Safety and Tolerability Profile: Frequency and severity of any treatment-emergent adverse events (TEAEs). (Time Frame: Throughout the 12-month study period).