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Efficacy and safety of daily paroxetine 20 mg and on-demand lidocaine spray combination in the treatment of premature ejaculation

Submission date
16/07/2025

Recruitment status
No longer recruiting

Registration date
25/07/2025

Overall study status
Completed

Last Edited
21/07/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Premature ejaculation (PE) is a prevalent sexual dysfunction affecting men, significantly impacting their quality of life and intimate relationships. Current treatments often focus on monotherapy, which may not address the condition comprehensively. This study aims to evaluate the efficacy and safety of a dual-treatment approach combining daily Paroxetine (20 mg) and on-demand Lidocaine spray in men diagnosed with PE and concomitant erectile dysfunction. The primary objective is to assess improvements in intravaginal ejaculatory latency time (IELT) and patient-reported outcomes, such as sexual satisfaction and control over ejaculation.

Who can participate?
Men aged 18–65 years with a clinical diagnosis of lifelong or acquired PE, as defined by the International Society for Sexual Medicine (ISSM), and a Premature Ejaculation Diagnostic Tool (PEDT) score ≥11 are eligible. Participants must have a stable heterosexual relationship for over six months, an International Index of Erectile Function-Erectile Function (IIEF-EF) score >21, and commit to sexual intercourse twice weekly during the study. Exclusion criteria include urological or neurological disorders, severe psychiatric conditions, allergies to SSRIs or lidocaine, and recent use of medications affecting sexual function.

What does the study involve?
Participants will receive daily oral Paroxetine (20 mg) and apply 10% Lidocaine spray to the glans penis before intercourse. At baseline, demographic data, IELT, PEDT, Premature Ejaculation Profile (PEP), and IIEF-EF scores will be recorded. Follow-up assessments will occur after four weeks to measure changes in IELT, PEP scores, and adverse effects. Compliance and treatment satisfaction will also be evaluated.

What are the possible benefits and risks of participating?
Benefits include potential improvements in ejaculatory control, sexual satisfaction, and relationship quality. Risks may involve side effects such as headache, flushing, or local irritation from Lidocaine. Severe adverse effects, though rare, could include allergic reactions or SSRI-

related symptoms (e.g., nausea, drowsiness). Participants may withdraw at any time if side effects are intolerable.

Where is the study run from?
The study is conducted at the Andrology Clinic of Memorial Hospital, Turkiye, in accordance with ethical guidelines approved by the hospital's Ethics Committee (Approval No: 2024/140).

When is the study starting and how long is it expected to run for?
June 2024 to December 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
For further information or participation inquiries, please contact the corresponding author at the Memorial Hospital Andrology Clinic. Contact details are available upon request through the hospital's administrative office.

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
140/2024

Study information

Scientific Title
Dual approach to ejaculatory control: daily paroxetine and on-demand lidocaine spray for treating premature ejaculation

Study objectives

This study aims to evaluate the efficacy and safety of a combined treatment modality using daily paroxetine 20 mg and on-demand lidocaine spray in men diagnosed with both erectile dysfunction and premature ejaculation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/06/2024, Memorial Hospital (Burhaniye Mah. Nagehan Sk. A Apt. No: 4 A / 1 34476 , Istanbul, 34036, Türkiye; +90 212 444 7888; editor@memorail.com.tr), ref: 140

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Premature ejaculation

Interventions
After obtaining detailed medical and sexual history of the patients, a physical examination was performed. Intravaginal ejaculation delay times (IELT) were recorded to clarify the PE diagnosis of the patients and premature ejaculation diagnostic tool (PEDT), premature ejaculation profile (PEP) and International Index of Erectile Function-Erectile Function subscale (IIEF-EF) questionnaire forms were filled. Patients with PEDT ≥11 were included in the study. Patients were asked to use daily 20 mg paroxetine (Paxil 20 mg tb, Pharmactive) and 10% lidocaine spray (Precoxin, Aymed Drug, Turkiye) before intercourse. Patients were called for a control visit 4 weeks after receiving treatment and IELT scores were recorded. In addition, the PEP questionnaire form was evaluated again. Side effects that developed during treatment were also recorded.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Paroxetine, lidocaine

Primary outcome(s)
Before and after treatment:
1. Intravaginal ejaculation latency time (IELT) will be assessed in seconds as an estimated outcome.
2. Premature Ejaculation Profile: This is a questionnaire consisting of four questions.

Key secondary outcome(s))
Side effects will be recorded and reported throughout the treatment period.

Completion date
10/12/2024

Eligibility

Key inclusion criteria
1. Men aged 18-65 years
2. Those who have had a heterosexual relationship with a single partner for more than 6 months at the time of enrollment and will continue this relationship throughout the study
3. Patients with a clinical diagnosis of erectile dysfunction and an IIEF score of >21
4. Those with a premature ejaculation score of ≥11
5. Patients and their partners agreeing to have sexual intercourse two times per week during the study period
6. Patients who commit to comply with the study protocol
7. Patients who sign an informed consent form
8. Patients who describe lifelong and acquired PE according to the definition of the International Society for Sexual Medicine (ISSM)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
Male

Total final enrolment
83

Key exclusion criteria
1. Those with a history of urological surgery, anatomic abnormality, or neurological disorders (e. g., multiple sclerosis), trauma or infection that may be associated with the development of premature ejaculation symptoms and is thought to be a potential cause of premature ejaculation
2. Those with a genital anomaly other than penile curvature that does not prevent sexual intercourse
3. Those who develop ED or PE due to drug withdrawal or drug use
4. Those whose spouses have any problems with sexual intercourse

5. Those with a history of severe psychiatric illness or suicide attempt
6. Those with a history of epilepsy
7. Those with a history of stroke, myocardial infarction, heart failure, unstable angina, life-threatening arrhythmia, or hypotension in the last 6 months
8. Those who are not suitable for sexual intercourse due to existing health problems
9. Those with resting systolic/diastolic blood pressure <90/50 mmHg and <170/100 mmHg
10. Those with a history of allergy to SSRIs and lidocaine-containing drugs
11. Continuing to use or discontinuing within the last 14 days, drugs such as monoamine oxidase inhibitors (MAOI), thioridazine, selective serotonin reuptake inhibitors (SSRIs), selective-norepinephrine reuptake inhibitors (SNRIs), serotonergic drugs/herbal products, tricyclic antidepressants, and atypical antipsychotics
12. Nitrates, alpha blockers, vasodilators, ketoconazole, itraconazole, ritonavir, saquinavir, telithromycin, nefazadone, nelfinavir, atazanavir, cimetidine, erythromycin, clarithromycin, fluconazole, amprenavir, fosamprenavir, aprepitant, verapamil, diltiazem, any vasodilator, antiplatelet, anticoagulant, dapoxetine, PDE5 inhibitors, alcohol, and stimulant drug users
13. Alcohol and drug addicts
14. Patients with premature ejaculation diagnosis receiving other forms of therapy (behavioral therapy or other locally applied medications)
15. Those who may receive medication that may affect the pharmacokinetic/pharmacodynamic properties of the study drugs during the study period
16. Patients with clinically defined symptoms of prostatitis
17. Those with thyroid hormone disorders

Date of first enrolment
01/07/2024

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
Türkiye

Study participating centre
Memorial Hospital
Istanbul
Türkiye
34075

Sponsor information

Organisation
Memorial Hospital Institutional Review Board

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date