Participant Information Sheet and Informed Consent

Study Title

A Comparative Double-Blind Randomized Study Between Proctofiz MD and Topical Nifedipine for the Treatment of Chronic Anal Fissure

Invitation

You are invited to participate in a research study because you have been diagnosed with chronic anal fissure. Participation is voluntary.

Purpose

The purpose of the study is to compare the efficacy and safety of Proctofiz MD with topical nifedipine in the treatment of chronic anal fissure.

Study Procedures

If you agree to participate, you will be randomly assigned (1:1) to receive one of the two study ointments. Neither you nor the study team will know which treatment you receive. The ointment is applied three times daily for six weeks. Follow-up includes clinic visits and telephone contacts according to the approved protocol.

Risks

Both treatments are approved topical therapies. Possible local burning or irritation may occur. Mild headache may occur with nifedipine-containing ointment. Unknown risks cannot be completely excluded.

Benefits

You may or may not benefit directly. Information obtained may improve future treatment of patients with chronic anal fissure.

Alternatives

You may choose standard medical therapy or other treatments discussed with your treating physician without participating in this study.

Confidentiality

Your personal information will be kept confidential and handled according to applicable regulations.

Voluntary Participation

Participation is voluntary. You may withdraw at any time without affecting your medical care.

Contacts

For questions regarding the study, please contact the Principal Investigator using the contact details approved by the Ethics Committee.

Consent

I have read the information above, had the opportunity to ask questions, and voluntarily agree to participate in this study.

Participant Name: _____
Signature: _____ Date: _____

Principal Investigator / Delegate: _____
Signature: _____ Date: _____