Primary Care dySpEpsia rikkuNshiTo

NCT06482671

Status	RECRUITING
Phase	Phase 3
Sponsor	Universitaire Ziekenhuizen KU Leuven
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (6)

• Voluntary written informed consent of the participant or their legally authorized representative has been obtained prior to any screening procedures

• Use of highly effective methods of birth control; defined as those that, alone or in combination, result in low failure rate (i.e., less than 1% per year) when used consistently and correctly; such as implants, injectables, combined oral contraceptives, some IUDs, true sexual abstinence (i.e. refraining from heterosexual intercourse during the entire period of risk associated with the Trial treatment(s)) or commitment to a vasectomised partner.

• Male or female

• years old or older

• Newly to be treated FD diagnosis

... and 1 more (see full listing online)

Exclusion (2)

• \. Participant has a history of diabetes mellitus type 1, type 2 (including therapy), eosinophilic esophagitis, coeliac disease or inflammatory bowel disease, major abdominal surgery (except for appendectomy, cholecystectomy or splenectomy).

• \. Any disorder, which in the Investigator's opinion might jeopardise the participant's safety or compliance with the protocol 3. Any prior or concomitant treatment(s) that might jeopardise the participant's safety or that would compromise the integrity of the Trial 4. If applicable: Female who is pregnant, breast-feeding or intends to become pregnant or is of child-bearing potential and not using an adequate, highly effective contraceptive 5. Patients with predominant symtoms of gastro-oesophageal reflux disease (GERD) or irritable bowel syndrome (IBS) 6. Patients with any active somatic or psychiatric condition that may explain dyspeptic symptoms (stable dose of single antidepressant allowed for psychiatric indication, no limitation for other indications) or severe depression using PHQ-7 (score of 20-27) 7. Patients already on PPI therapy20 or using a PPI in the last 2 weeks prior to enrolment 8. Patients with active malignancy (including therapy) 9. Known HIV, HBV, or HCV infection (including therapy) 10. Significant alcohol use (more than 10 units a week) 11. Known allergy to Rikkunshito or any of its ingredients 12. Patients with overweight (BMI\>26)

Locations (1 total)

KU Leuven, Leuven, Vlaams-Brabant, Belgium