# Evaluating the Efficacy and Tolerability of ZED1227 in Subjects With Non-responsive Celiac Disease

NCT07298343

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| **Status** | RECRUITING |
| **Phase** | Phase 2 |
| **Sponsor** | Dr. Falk Pharma GmbH |
| **Enrollment** | 356 participants |

## Key Eligibility Criteria

### Inclusion (5)

- Signed informed consent
- Men or women between 18 and 80 years of age, inclusively
- Documented initial biopsy-proven diagnosis of celiac disease or, in case of missing histological documentation, TG2-IgA \> 10 x upper limit of normal (ULN) at diagnosis at least 12 months prior to V0
- Adherence to a gluten-free diet (GFD) for at least 12 months prior to V0
- Human leukocyte antigen DQ (HLA-DQ) typing compatible with celiac disease

### Exclusion (5)

- Presence of hypo- or hyperthyroidism. A patient with a well-controlled thyroid disorder during the previous 3 months can be included
- Patients diagnosed to have confirmed refractory celiac disease type I (RCDI) or II (RCDII), with the exception that patients with a diagnosis of RCDI can be considered for inclusion if they do not have clear signs of T cell monoclonality or atypical T cells (e.g., as revealed by CD3/CD8 immunohistochemistry) and if they do not present with very severe symptoms and/or parameters of significant malabsorption and if they have not received prior treatment with immunosuppressants such as budesonide or azathioprine,
- Severe complications of celiac disease
- Concomitant diseases of the intestinal tract in addition to celiac disease, such as Crohn's disease, ulcerative colitis, other forms of inflammatory bowel disease, severe irritable bowel syndrome, microscopic colitis, small intestinal bacterial overgrowth (SIBO), exocrine pancreatic insufficiency; any other active diseases of the intestinal tract (e.g., active, untreated peptic ulcer, esophagitis, gastroesophageal reflux disease) that might, in the investigator's opinion, interfere with assessment of symptoms of abdominal pain, diarrhoea, or other components of celiac disease
- History or presence of dermatitis herpetiformis

## Locations (1 total)

University Medical Center Mainz, Mainz, Germany