ISRCTN79155276 https://doi.org/10.1186/ISRCTN79155276

A study to learn if ZED1227 can improve continued celiac disease symptoms despite a gluten-free diet

Submission date 09/01/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/03/2024	**Overall study status** Ongoing	
Last Edited 22/09/2026	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
This study is investigating if the study drug, ZED1227 (an oral capsule), can help reduce the symptoms and damage to cells in the intestine caused when coeliac disease sufferers eat gluten. ZED1227 will be compared with a 'placebo' which will help better assess its effects and side effects. A 'placebo' looks identical to the ZED1227 capsule but contains no active study drug substance.

Who can participate?
Patients 18-80 years old who have had coeliac disease for at least 12 months and, despite being on a gluten-free diet for at least 12 months, still experience symptoms

What does the study involve?
Participants will be given either ZED1227 or a placebo. The study is divided into 2 cohorts: participants of the first cohort were included in this trial during the first half of the trial between June 2024 and January 2025 (called Cohort 0), and the treatment groups were ZED1227 at a dose of 75 mg/day or placebo. In the second cohort (called Cohort 1), the treatment groups are ZED1227 in doses of 100mg/day, 200mg/day and 50 mg/day or placebo. Participants were/will be divided into treatment groups by randomisation. Randomisation is the assignment of a subject to a treatment group by chance (like tossing a coin). Randomisation will be performed electronically; neither the participant nor the study doctor can influence which treatment group is assigned.
Participants take ZED1227 or placebo once a day (three times a day in cohort 0) with a meal and eat a gluten-containing snack bar three times a week (this mimics unintended gluten exposure). Before randomisation into the study, participants will be asked to eat a gluten-free snack bar to make sure they can tolerate the ingredients other than gluten.
Study participation will last about 23 weeks and will involve seven visits to the study site. At these visits, the participant will have procedures performed, including collection of blood and urine samples; they will be asked to complete study questionnaires and discuss their medication and health. Two gastrointestinal endoscopies with biopsies will be required; one at the start of the study and another at the end. For the duration of the study, the participants will be asked to

complete an electronic diary, recording, for example, when they took their medication, their coeliac symptoms and health issues experienced. Some participants can agree to take part in a study exit interview.

What are the possible benefits and risks of participating?
Participants may have an allergic reaction to the snack bar which is eaten as part of the study to provide gluten exposure. Actions to prevent an allergic reaction or mitigate symptoms that may arise include incorporating an exclusion criterion for participants with food allergies to any of the snack bar ingredients, informing the participant in the PIS of the ingredients of the snack bar and having the participant eat a snack bar (minus the gluten) whilst observed in clinic as part of the screening visit to ensure they can tolerate it.
The gluten-containing snack bar may exacerbate the participants' symptoms in response to gluten, this cannot be avoided as the study drug's effect on these symptoms is what is being studied. Upon discontinuation of snack bars, the symptoms will resolve. These symptoms, occurrence and severity are recorded by the subject and reviewed as part of the study. There is also an exclusion criterion for patients who have known hypersensitivity and/or allergy to wheat and/or gluten.
Participants may experience side effects to the study drug, they are questioned at each visit on their health status, and they are instructed in the PIS and at the visits to contact the site should they have any severe reactions/illnesses. Patients with known intolerance/hypersensitivity /resistance to the study drug, its excipients or drugs of a similar chemical structure are excluded from the study.
Upper gastrointestinal endoscopy might cause bleeding that may need medical attention, this is a rare complication. Other severe side effects, such as perforations resulting from the procedure, are reported in 0.04% to 0.01% of endoscopies. Endoscopies are performed as they would be in normal clinical practice with the same safeguards and any necessary follow-up. Participants should contact the site if they feel unwell after their endoscopy. Endoscopies are invasive procedures but are required to see if the study drug has an effect on the gut morphology, this is a study endpoint.
Blood sampling might cause discomfort, bruising, clotting of the vein at the needle insertion site (unusual), venous inflammation (thrombophlebitis) or nerve injury. Site staff will be trained and will endeavour to cause as little pain as possible and to cause no serious injury.
The participants are expected to keep a diary detailing when they take the study medication and any gluten-related symptoms they experience. They also have a number of questionnaires to complete. This can all be a bit onerous, however, the diary can be accessed on the participant's mobile phone or computer and thus is easy to access and the site staff will provide training to the participant on how to use the device. Diary entries mainly require ticking certain boxes. The questionnaires are largely multiple choice and no lengthy text input is required from the participant.
There is a possibility of breach of confidentiality, but as all staff are trained healthcare or allied healthcare professionals, trained in the processes for clinical trials, are aware of GDPR and work to their site’s/company’s SOPs, this risk is minimal.

Where is the study run from?
Dr Falk Pharma (Germany)

When is the study starting and how long is it expected to run for?
March 2024 to October 2027

Who is funding the study?
Dr Falk Pharma (Germany)

Who is the main contact?
Beate Niemeier
Dr. Falk Pharma, Leinenweberstraße 5, 79108 Freiburg, Germany
+49 761 15140
Beate.niemeier@drfalkpharma.de

Contact information

Type(s)
Scientific

Contact name
Dr Beate Niemeier

Contact details
Dr. Falk Pharma
Leinenweberstraße 5
79108
Germany
Freiburg
+49 (0)761 15140
Beate.niemeier@drfalkpharma.de

Type(s)
Principal investigator

Contact name
Dr David Sanders

Contact details
Glossop Road
Sheffield
United Kingdom
S10 2JF
+44 (0)114 226 1179
david.sanders1@nhs.net

Additional identifiers

ClinicalTrials.gov (NCT)
NCT07298343

Clinical Trials Information System (CTIS)
2023-506150-21

Integrated Research Application System (IRAS)
1008894

Central Portfolio Management System (CPMS)
59048

Sponsor's protocol serial number
CEC-013/CEL

Study information

Scientific Title
A Phase II, double-blind, randomised, placebo-controlled trial to evaluate the efficacy and tolerability of ZED1227 in celiac disease subjects experiencing symptoms despite gluten-free diet

Study objectives
The main objective of this study is to establish how effective ZED1227 is at stopping or reducing the symptoms of coeliac disease.

The secondary objectives are:
1. To assess how effective ZED1227 is at stopping or reducing cell damage in the gut due to eating gluten
2. To assess how effective ZED1227 is at reducing non-stool-related symptoms of coeliac disease such as abdominal pain, bloating and nausea
3. To assess how safe it is to take ZED1227 and if taking it causes any side effects

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/02/2024, London - City and East Research Ethics Committee (Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8144; cityandeast.rec@hra.nhs.uk), ref: 24/LO/0071

Primary study design
Interventional

Study design
Randomized placebo-controlled double-blind parallel-group trial

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Coeliac disease

Interventions
Current interventions as of 01/09/2026:
During this clinical study, ZED1227 will be compared with a placebo. This comparison is intended to better assess the effects and side effects of ZED1227. A placebo capsule looks identical to a ZED1227 capsule but contains no active study drug substance. The study is divided into 2 cohorts: Participants in the first cohort were included in this trial during the first half of the trial, between June 2024 and January 2025 (called Cohort 0), and the treatment groups were ZED1227 at a dose of 75 mg/day or placebo. In the second cohort (called Cohort 1), the treatment groups were ZED1227 at doses of 100mg/day, 200mg/day and 50 mg/day or placebo.

The study treatment group received by the participant (ZED1227 at a specific dose or placebo) is decided by a predetermined random procedure, such as tossing a coin; this is called randomisation. The randomisation is performed by an electronic procedure. Neither the participant nor the study doctor can influence which treatment group is assigned.

Before randomisation into the study, participants will be asked to eat a gluten-free snack bar to make sure they can tolerate its ingredients other than gluten. If the participant is suitable for the study, they will start taking the gluten-containing snack bar three times a week (this ensures gluten exposure).

Previous interventions:
Participants will be divided into two or three treatment groups. During this clinical study, ZED1227 will be compared with a placebo. This comparison is intended to better assess the effects and side effects of ZED1227. A placebo capsule looks identical to a ZED1227 capsule but contains no active study drug substance. Participants will be given either ZED1227 or a placebo. Optionally, a third study arm might be opened during the study, where patients receive a reduced ZED1227 dose. The study drug received will be decided by a predetermined random procedure like tossing a coin; this is called randomisation. The optional third treatment group will be added if data from another ongoing study supports it. If there are only two treatment groups, half of the participants will be given the study drug and the other half of the participants will receive a placebo. If the optional third group is added, two-thirds of the subjects will be given the study drug. Before randomisation into the study, participants will be asked to eat a gluten-free snack bar to make sure they can tolerate ingredients other than gluten. If the participant is suitable for the study, they will start taking the gluten-containing snack bar three times a week.

The randomisation (i.e., assignment of a subject to one of the treatment groups by chance) will be performed by an electronic procedure. Neither the participant nor the study doctor can influence which treatment group is assigned.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
ZED1227

Primary outcome(s)
Coeliac Disease Symptom Diary (CDSD) GI-specific Symptom Score at Baseline Visit B (V2, week 3) to V5 (week 15). Weekly symptom-specific scores for diarrhoea, abdominal pain, bloating, nausea, and tiredness will be calculated from daily average scores (0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe). A weekly GI severity score will include diarrhoea, abdominal pain, bloating, and nausea. The higher the score, the more severe the coeliac disease symptoms.

Key secondary outcome(s)
1. The efficacy of ZED1227 capsules for changes in Gl symptoms measured using the difference in mean change percentage of symptom free days over a 14-day period and change in Coeliac Disease Symptom Diary Non-Stool GI Symptom Score, symptoms recorded at daily timepoints

2. Effect of each prespecified dose of ZED1227 compared with placebo on duodenal mucosal morphology measured using digital morphometry of formalin-fixed samples as the change in villous height:Crypt Depth (VH:CrD) and proportion of subjects with histologic non-worsening (defined as a change in VH:CrD ≥ 0 from baseline) at baseline Visit A (V1, Wk 0) and V5 (Wk 15)

3. The effect of each prespecified dose of ZED1227 compared with placebo on mucosal inflammation measured using the change in density of cluster of differentiation 3- positive Intraepithelial Lymphocytes at baseline Visit A (V1, Wk 0) and V5 (Wk 15)

4. The effect of each prespecified dose of ZED1227 compared with placebo on celiac-related serology measured using the change in serological markers TG2-IgA, TG2-IgG, DGP-IgA, DGP-IgG, and EmA-IgA at baseline Visit B (V2, Wk 3), V5 (Wk 15) and V6 (Wk 16)

Previous key secondary outcomes as of 22/09/2026:
1. Villous Height to Crypt Depth ratio (VH: CrD) measured using digital morphometry of formalin-fixed samples from Baseline Visit A from Week 0 to Week 15
2. Non-stool GI symptoms measured using the CDSD Non-Stool GI Symptom Score (abdominal pain, bloating, nausea) from Week 3 to Week 15. A weekly Non-Stool GI Severity Score will be calculated for non-stool GI symptoms (i.e., abdominal pain, bloating and nausea) from daily average scores (0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe). The higher the score, the more severe the coeliac disease symptoms.
3. Duodenal mucosal inflammation measured as the density of CD3-positive intraepithelial lymphocytes (IELs) from Baseline Visit A (V1, Week 0) to V5 (Week 15)

Completion date
31/10/2027

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 01/09/2026:
1. Signed informed consent
2. Men or women between 18 and 80 years of age, inclusively
3. Documented initial biopsy-proven diagnosis of coeliac 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
4. Adherence to a gluten-free diet (GFD) for at least 12 months prior to V0
5. Human leukocyte antigen DQ (HLA-DQ) typing compatible with coeliac disease
6. At least one moderate or severe gastrointestinal symptom (i.e., diarrhoea, abdominal pain, bloating, or nausea) during the last 4 weeks prior to Baseline Visit A and last 3 weeks prior to Baseline Visit B as a GI total mean symptom score (measured using CDSD) for the worst 25% of the days of ≥ 2 on a 5-point scale. The interval between Screening Visit and Baseline Visit A must be at least 28 days. If the interval is less than 28 days, this inclusion criterion is not met.
7. Biopsy showing VH:CrD ratio of ≤ 2.5 from distal duodenum biopsies in Trial Period A
8. Negative diagnosis of Helicobacter pylori infection and no history of eradication within the last 2 months before biopsy sampling in Trial Period A
9. BMI between 17.0 and 35 kg/m², inclusively
10. Willingness to follow her/his usual dietary patterns, including eating at restaurants and others' homes during the trial
11. Willingness to maintain current GFD throughout participation in the trial

12. Negative pregnancy test in female subjects under 60 years of age at Screening Visit and Baseline Visit B
13. Women of child-bearing potential should use a highly effective method of birth control, which is defined as those which result in a low failure rate (i.e. less than 1% per year) when used consistently and correctly, such as implants, injectables, combined oral contraceptive pills, combined contraceptive patches and vaginal rings, copper-containing intrauterine devices, sexual abstinence or vasectomised partner. Abstinence alone is not considered an acceptable form of contraception. The investigator is responsible for determining whether the subject has adequate birth control for trial participation.

Previous key inclusion criteria:
1. Signed informed consent
2. Men or women between 18 and 80 years of age, inclusively
3. Documented initial biopsy-proven diagnosis of coeliac 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
4. Adherence to a gluten-free diet (GFD) for at least 12 months prior to V0
5. Human leukocyte antigen DQ (HLA-DQ) typing compatible with coeliac disease
6. At least one moderate or severe gastrointestinal symptom (i.e., diarrhoea, abdominal pain, bloating, or nausea) during the last 4 weeks prior to Baseline Visit A and last 3 weeks prior to Baseline Visit B as a GI total mean symptom score (measured using CDSD) for the worst 25% of the days of ≥ 2 on a 5-point scale
7. Biopsy showing VH:CrD ratio of ≤ 2.5 from distal duodenum biopsies in Trial Period A
8. Negative diagnosis of Helicobacter pylori infection and no history of eradication within the last 2 months before biopsy sampling in Trial Period A
9. BMI between 17.0 and 35 kg/m², inclusively
10. Willingness to follow her/his usual dietary patterns, including eating at restaurants and others' homes during the trial
11. Willingness to maintain current GFD throughout participation in the trial
12. Negative pregnancy test in female subjects under 60 years of age at Screening Visit and Baseline Visit B
13. Women of child-bearing potential should use a highly effective method of birth control, which is defined as those which result in a low failure rate (i.e. less than 1% per year) when used consistently and correctly, such as implants, injectables, combined oral contraceptive pills, combined contraceptive patches and vaginal rings, copper-containing intrauterine devices, sexual abstinence or vasectomised partner. The investigator is responsible for determining whether the subject has adequate birth control for trial participation.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit

80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 01/09/2026:
1. Presence of hypo- or hyperthyroidism. A patient with a thyroid-stimulating hormone (TSH) level up to 25% higher than ULN or up to 25% lower than the lower limit of normal (LLN), but with normal free triiodothyronine (FT3) and free thyroxine (FT4) levels, can be included in the trial. A patient with a well-controlled thyroid disorder during the previous 3 months can be included.
2. Patients diagnosed with confirmed refractory coeliac disease type I (RCDI) or II (RCDII), with the exception that patients with a diagnosis of RCDI can be included if they don't have clear signs of T cell monoclonality or atypical T cells (e.g., as revealed by CD3/CD8 immunohistochemistry) & if they don't present with very severe symptoms &/or parameters of significant malabsorption & if they haven't received prior treatment with immunosuppressants e. g. budesonide or azathioprine.
3. Severe complications of coeliac disease (e.g., enteropathy-associated T-cell lymphoma [EATL], ulcerative jejunitis, perforation)
4. Concomitant diseases of the intestinal tract, e.g. 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.
5. History/presence of dermatitis herpetiformis
6. History/presence of neurological disorders like ataxia or neuropathy (mild neuropathy, related or unrelated to celiac disease, is not a reason for exclusion)
7. Any severe concomitant cardiovascular, renal, endocrine (type 1 diabetes mellitus with HbA1C >8% / 64 mmol/mol or hospitalisation or emergency visit for hyperglycaemia or hypoglycaemia within 12 months of screening), or any significant complication associated with previous EGD), ASA physical status grade 3 or higher, or psychiatric disorder or other
diseases, which in the opinion of the investigator might have an influence on the subject's compliance or the interpretation of the results or the subject's ability to safely participate in all elements of the study protocol including procedures.
8. Any prior invasive malignancy diagnosed within the last 5 years prior to Screening visit. Patients with basal cell carcinoma of the skin completely resected can be included.
9. Evidence of relevant systemic disease (e.g., active tuberculosis)
10. Abnormal hepatic function [alkaline aminotransferase (ALT) or alkaline phosphatase (ALP) > 2.5 x ULN], liver cirrhosis, or portal hypertension.
11. Glomerular filtration rate ≤ 60 ml/min/1.73 m^2
12. Continuous intake of systemic (oral/intravenous) corticosteroids or immunomodulators (e.g., glucocorticoids, cyclosporine, methotrexate, anti-TNF-α therapy, anti-integrin therapy, Janus kinase inhibitors), high-dose inhaled corticosteroids (> 1000 µg/d of beclomethasone dipropionate or equivalent) during the past 3 months before V0.
13. Continuous intake of drugs with suspicion of impact on villous atrophy, such as:

13.1. Proton-pump inhibitors (PPIs; permitted at a regular dose equivalent to 20-40 mg/day pantoprazole, esomeprazole or equivalent)
13.2. Selective serotonin reuptake inhibitors (SSRIs; low to medium dose [10-150 mg Fluvoxamine or equivalent dose of other SSRIs] permitted in case of long-term therapy [at least for 6 months])
13.3. Losartan (angiotensin II receptor blockers equivalent to 50 mg losartan permitted except for olmesartan forbidden at any dose)
13.4. Mycophenolate (forbidden at any dose) during the past 2 months before biopsy sampling in Trial Period A
13.5. Non-steroidal anti-inflammatory drugs (NSAIDs; maximal daily dose permitted 900 mg for ibuprofen, 500 mg for naproxen and 75 mg for diclofenac, except for one week before biopsy)
13.6. Acetylsalicylic acid (max daily dose permitted 100 mg) during the past 4 weeks before biopsy sampling at Baseline Visit A
14. Alcohol use > 12 g/d for women, >24 g/d for men within the past 12 months before screening
15. Dual antiplatelet therapy (i.e., acetylsalicylic acid in combination with thienopyridines [clopidogrel, prasugrel, ticlopidine or ticagrelor]) or oral anticoagulants (i.e., warfarin, dabigatran, etexilate, rivaroxaban, apixaban)
16. Unwillingness to undergo gastrointestinal endoscopy with biopsy as required per protocol
17. Unwillingness to ingest SIGE bars as required per protocol
18. Allergies to SIGE bar non-gluten ingredients (tapioca syrup, oats, almonds, rice crisp, chocolate, almond butter, cocoa butter, oat flour, glycerine, sunflower lecithin, salt, & natural flavours) or significant symptoms on eating the gluten-free SIGE bar
19. Known hypersensitivity reaction &/or allergy, including anaphylaxis, to wheat &/or gluten
20. If more than 10% of planned enrolled subjects report a greater than 1 point improvement in PGI-S during Trial Period A, further subjects with >1 point improvement in PGI-S will be excluded
21. Known intolerance/hypersensitivity/resistance to the study drug & excipients or drugs of similar chemical structure/pharmacological profile
22. Doubt about the subject's cooperation, e.g., because of addiction to alcohol or drugs
23. Existing or intended pregnancy or breastfeeding
24. Affiliation with the investigator: Close affiliation with the investigator (e.g., a close relative) or persons working at the study sites (if financially dependent on the investigator) or subject who is an employee of the Sponsor's company
25. Subjects who are institutionalised because of legal/regulatory order
26. Participation in another trial of a therapeutic who received IMP within the last 30 days prior to V0 or within 5 half-lives of IMP (whichever is longer), or any previous participation in another clinical trial related to celiac disease within 12 months prior to screening, or simultaneous participation in another clinical intervention trial, or any prior exposure to ZED1227.
27. Concomitant treatment with P-gp inhibitors, concomitant treatment with strong CYP3A4 inhibitors, or use of either P-gp inhibitor or strong CYP3A4 inhibitor within ≤ 5 half-lives of the specific inhibitor prior to screening.

Previous key exclusion criteria:
1. Presence of hypo- or hyperthyroidism. A patient with a well-controlled thyroid disorder during the previous 3 months can be included.
2. Patients diagnosed with confirmed refractory coeliac disease type I (RCDI) or II (RCDII), with the exception that patients with a diagnosis of RCDI can be included if they don't have clear signs of T cell monoclonality or atypical T cells (e.g., as revealed by CD3/CD8 immunohistochemistry) & if they don't present with very severe symptoms &/or parameters of significant malabsorption & if they haven't received prior treatment with immunosuppressants e. g. budesonide or azathioprine.
3. Severe complications of coeliac disease
4. Concomitant diseases of the intestinal tract, e.g. Crohn's disease, ulcerative colitis, severe

irritable bowel syndrome, microscopic colitis, small intestinal bacterial overgrowth, exocrine pancreatic insufficiency
5. History/presence of dermatitis herpetiformis.
6. History/presence of neurological disorders like ataxia or neuropathy
7. Any severe concomitant cardiovascular, renal, endocrine (type 1 diabetes mellitus with HbA1C >8% / 64 mmol/mol or hospitalisation or emergency visit for hyperglycaemia or hypoglycaemia within 12 months of screening), or psychiatric disorder or other disease.
8. Any prior invasive malignancy diagnosed within the last 5 years prior to Screening visit. Patients with basal cell carcinoma of the skin completely resected can be included.
9. Evidence of relevant systemic disease (e.g., active tuberculosis)
10. Abnormal hepatic function [alkaline aminotransferase (ALT) or alkaline phosphatase (ALP) > 2.5 x ULN), liver cirrhosis, or portal hypertension.
11. Glomerular filtration rate ≤ 60 ml/min/1.73 m²
12. Continuous intake of systemic (oral/intravenous) corticosteroids or immunomodulators (e.g., glucocorticoids, cyclosporine, methotrexate, anti-TNF-α therapy, anti-integrin therapy, Janus kinase inhibitors), high dose inhaled corticosteroids during the past 3 months before V0.
13. Continuous intake of drugs with suspicion of impact on villous atrophy, e.g.
14. Alcohol use > 12 g/d for women, >24 g/d for men within the past 12 months before screening.
15. Dual antiplatelet therapy or oral anticoagulants
16. Unwillingness to undergo gastrointestinal endoscopy with biopsy as required per protocol
17. Unwillingness to ingest SIGE bars
18. Allergies to SIGE bar nongluten ingredients (tapioca syrup, oats, almonds, rice crisp, chocolate, almond butter, cocoa butter, oat flour, glycerine, sunflower lecithin, salt, & natural flavours) or significant symptoms on eating the gluten-free SIGE bar
19. Known hypersensitivity reaction &/or allergy, including anaphylaxis, to wheat &/or gluten
20. If more than 10% of planned enrolled subjects report a greater than 1 point improvement in PGI-S during Trial Period A, further subjects with >1 point improvement in PGI-S will be excluded
21. Known intolerance/hypersensitivity/resistance to the study drug & excipients or drugs of similar chemical structure/pharmacological profile.
22. Doubt about the subject's cooperation, e.g., because of addiction to alcohol or drugs
23. Existing or intended pregnancy or breastfeeding
24. Affiliation with the investigator or persons working at the study sites or subject who is employed by the Sponsor
25. Subjects who are institutionalised because of legal/regulatory order
26. Participation in another trial of a therapeutic who received IMP within the last 30 days prior to V0

Date of first enrolment
31/03/2024

Date of final enrolment
01/04/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Australia

Austria

Croatia

Finland

Georgia

Germany

Ireland

Italy

New Zealand

Norway

Poland

Romania

Spain

Sweden

Switzerland

United States of America

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
S10 2JF

Study participating centre
Synexus Wales Clinical Research Centre
2 Riverside Court
Gwaelod-y-Garth
Cardiff
Wales
CF15 9SS

Study participating centre
Synexus Manchester Clinical Research Centre
Kilburn House
Lloyd Street North
Manchester
England
M15 6SE

Study participating centre
Synexus Merseyside Clinical Research Centre
Burlington House
Crosby Road North
Waterloo
Liverpool
England
L22 0LG

Study participating centre
Synexus North East Clinical Research Centre
Hexham General Hospital
Corbridge Road
Hexham
England
NE46 1QJ

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Synexus Scotland Clinical Research Centre
Ground Floor
Fleming House
Phoenix Crescent

Bellshill
Scotland
ML4 3NJ

Sponsor information

Organisation
Dr Falk Pharma (Germany)

ROR
https://ror.org/05sh9vm75

Funder(s)

Funder type
Industry

Funder Name
Dr. Falk Pharma

Alternative Name(s)
Falk Pharma, Dr Falk Pharma, Dr Falk Pharma GmbH, Dr. Falk Pharma GmbH, Dr. Falk Pharma UK Ltd

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data will be stored in a non-publicly available repository at Dr. Falk Pharma, Freiburg, Germany, for 25 years and will then be erased or anonymised. The type of data stored will be Clinical data and diary/questionnaire answers, the data will be stored in a pseudonymized manner. Personal data will stay at the study site of the participant. Data will be published after the appropriate time for review and written agreement by Dr. Falk Pharma GmbH after the end of the trial. The data will be shared in a pseudonymized manner with parties working with the

Sponsor, with Ethics Committees and regulatory agencies in Europe, the USA, and other countries where the Sponsor seeks approval of this study or where the study is conducted, as well as to agencies responsible for marketing authorisation within and outside the EU, including the USA and other countries. Participants' consent has been obtained to pass data in a pseudonymized form to the aforementioned parties. The types of analyses and the mechanisms used for the analysis have not yet been defined.

IPD sharing plan summary

Stored in non-publicly available repository