Clinical trial results:
A double-blind, randomized, placebo-controlled, phase 2a study to evaluate the safety, tolerability, and pharmacodynamic (PD) effects of two infusions of escalating doses of TPM502 in adults diagnosed with celiac disease (CeD)

Summary

EudraCT number	2022-001656-41
Trial protocol	NO FI SE DE NL
Global end of trial date	08 August 2024

Results information

Result version number	v1 (current)
This version publication date	04 September 2025
First version publication date	04 September 2025

Trial information

Trial identification

Sponsor protocol code	TCeD21

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05660109
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Topas Therapeutics GmbH
Sponsor organisation address	Martinistrasse 64, Hamburg, Germany, 20251
Public contact	Veronica Asnaghi, Head of Clinical Science, Topas Therapeutics GmbH , asnaghi@topas-therapeutics.com
Scientific contact	Veronica Asnaghi, Head of Clinical Science, Topas Therapeutics GmbH , asnaghi@topas-therapeutics.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	11 July 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 August 2024
Global end of trial reached?	Yes
Global end of trial date	08 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of two infusions of escalating doses of TPM502 in CeD patients.

Protection of trial subjects:

No safety signal associated with the administration of the study drug has been documented. Nonetheless, acknowledging the early phase of clinical development, a number of activities were implemented to mitigate the potential risks of hypersensitivity reactions, cytokine release syndrome, hepatotoxicity and disease flare. They included the following:
• Patients with history of hypersensitivity to i.v. iron preparations were not eligible
• Patients were closely monitored for 6 hours post administration of IMP, and longer if needed, and were required to return to the site 24 hours post-IMP administration
• Sequential treatment of patients, starting with a sentinel patient at the first dose level, was foreseen
• Independent data monitoring committee (iDMC) review of data before the inception of dosing at the next dose level was foreseen
• Patients with active moderate to severe liver disease, iron-storage disease, or any disease requiring regular blood transfusions were excluded from this study
• Iron-related parameters were monitored during the study together with liver function tests with stopping rules in place should a patient develop signs of severe hepatotoxicity
• The planned gluten challenge could lead to onset/worsening of celiac disease symptoms, and for this reason patients developing intolerable symptoms after the screening GC were excluded from the study.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	01 December 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 2
Country: Number of subjects enrolled	Netherlands: 17
Country: Number of subjects enrolled	Norway: 8
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	Finland: 5
Worldwide total number of subjects	38
EEA total number of subjects	36

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	35
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Norway: 2 sites; regulatory approval 7/12/22; FPI 20/12/22
Germany: 1 site; reg. approval 21/4/23; FPI N/A
Finland: 2 sites; reg. approval 27/12/22; FPI 11/4/23
Netherlands: 1 site; reg. approval 22/2/23; FPI 14/3/23
Sweden: 1 site; reg. approval 24/4/23; FPI 29/6/23
Australia: 2 sites; reg. approval 16/10/23; FPI 6/12/23

Pre-assignment

Screening details:

391 patients were screened. Main reasons for screen failure were: not being HLA-DQ2.5 positive but HLA-DQ8 and HLA-DQ2.2 negative (35%) and not meeting the requirement to show IL-2 response post-gluten challenge above a pre-defined threshold (20%).

Pre-assignment period milestones

Number of subjects started	391[1]
Number of subjects completed	38

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Did not meet exclusion criteria: 49
Reason: Number of subjects	Did not meet inclusion criteria: 228
Reason: Number of subjects	Consent withdrawn by subject: 31
Reason: Number of subjects	Physician decision: 3
Reason: Number of subjects	Miscellaneous: 42

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Pre-assignment period is defined as all patients signing a consent form and being screened, while the number enrolled is defined as the number who met screening criteria and were randomised.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Blinding implementation details:

The CRO unblinded statistician, the unblinded monitor and the clinical sites´ personnel involved in IMP and placebo preparation were unblinded to the study treatment. The IMP and the placebo are of similar colour and appearance, and the blinded labels on the syringe containing either TPM502 or placebo were designed to prevent identification of the treatment of the patients to blinded personnel involved in the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	TPM502 0.72 µmol

Arm description:

Participants randomised to this arm received TPM502 at the total dose of 0.72 µmol in two divided doses (0.36 µmol each).
Each dose was prepared as a 30 mL solution for infusion.

Arm type	Experimental

Investigational medicinal product name	TPM502
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received TPM502 in two divided doses, two weeks apart.

Arm title	TPM502 2.4 µmol

Arm description:

Participants randomised to this arm received TPM502 at the total dose of 2.4 µmol in two divided doses (1.2 µmol each).
Each dose was prepared as a 30 mL solution for infusion.

Arm type	Experimental
Investigational medicinal product name	TPM502
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received TPM502 in two divided doses, two weeks apart.

Arm title	TPM502 4.8 µmol

Arm description:

Participants in this arm received TPM502 at the total dose of 4.8 µmol in two divided doses (2.4 µmol each).
Each dose was prepared as a 30 mL solution for infusion.

Arm type	Experimental
Investigational medicinal product name	TPM502
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received TPM502 in two divided doses, two weeks apart.

Arm title	TPM502 7.2 µmol

Arm description:

Participants randomised to this arm received TPM502 at the total dose of 7.2 µmol in two divided doses (3.6 µmol each).
Each dose was prepared as a 30 mL solution for infusion.

Arm type	Experimental
Investigational medicinal product name	TPM502
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received TPM502 in two divided doses, two weeks apart.

Arm title	Placebo

Arm description:

Ferinject solution diluted to 2 mg iron/ml was used as placebo and administered as 30 ml infusion. Ferinject, an iron preparation, was chosen as placebo in this study because of its visual characteristics (i.e., its colour), relevant to maintain the study blinding.

Arm type	Placebo

Investigational medicinal product name	Ferinject
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Ferinject solution diluted to 2 mg iron/ml was used as placebo and administered as 30 ml infusion.

Number of subjects in period 1	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol
Started	8	6	6
Completed 1st IMP dose (Day 1)	8	6	6
Completed 2nd IMP dose (Day 15)	7	6	6
Completed 2nd gluten challenge (Day 22)	7	6	6
Completed	7	6	6
Not completed	1	0	0
Consent withdrawn by subject	1	-	-

Number of subjects in period 1	TPM502 7.2 µmol	Placebo
Started	6	12
Completed 1st IMP dose (Day 1)	6	12
Completed 2nd IMP dose (Day 15)	6	12
Completed 2nd gluten challenge (Day 22)	6	12
Completed	6	12
Not completed	0	0
Consent withdrawn by subject	-	-

Baseline characteristics

Reporting groups	
Reporting group title	TPM502 0.72 µmol
Reporting group description:	
Participants randomised to this arm received TPM502 at the total dose of 0.72 µmol in two divided doses (0.36 µmol each). Each dose was prepared as a 30 mL solution for infusion.	
Reporting group title	TPM502 2.4 µmol
Reporting group description:	
Participants randomised to this arm received TPM502 at the total dose of 2.4 µmol in two divided doses (1.2 µmol each). Each dose was prepared as a 30 mL solution for infusion.	
Reporting group title	TPM502 4.8 µmol
Reporting group description:	
Participants in this arm received TPM502 at the total dose of 4.8 µmol in two divided doses (2.4 µmol each). Each dose was prepared as a 30 mL solution for infusion.	
Reporting group title	TPM502 7.2 µmol
Reporting group description:	
Participants randomised to this arm received TPM502 at the total dose of 7.2 µmol in two divided doses (3.6 µmol each). Each dose was prepared as a 30 mL solution for infusion.	
Reporting group title	Placebo
Reporting group description:	
Ferinject solution diluted to 2 mg iron/ml was used as placebo and administered as 30 ml infusion. Ferinject, an iron preparation, was chosen as placebo in this study because of its visual characteristics (i.e., its colour), relevant to maintain the study blinding.	

Reporting group values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol
Number of subjects	8	6	6
Age categorical Units: Subjects			
Age continuous			
Mean age (continuous)			
Units: years			
arithmetic mean	36.4	38.7	35.8
standard deviation	± 13.69	± 17.07	± 18.54
Gender categorical			
Gender			
Units: Subjects			
Female	6	5	4
Male	2	1	2

Reporting group values	TPM502 7.2 µmol	Placebo	Total
Number of subjects	6	12	38
Age categorical Units: Subjects			

Age continuous			
Mean age (continuous)			
Units: years			
arithmetic mean	44.2	37.4	
standard deviation	± 23.61	± 13.94	-
Gender categorical			
Gender			
Units: Subjects			
Female	3	9	27
Male	3	3	11

End points

End points reporting groups

Reporting group title	TPM502 0.72 µmol
Reporting group description:	
Participants randomised to this arm received TPM502 at the total dose of 0.72 µmol in two divided doses (0.36 µmol each). Each dose was prepared as a 30 mL solution for infusion.	
Reporting group title	TPM502 2.4 µmol
Reporting group description:	
Participants randomised to this arm received TPM502 at the total dose of 2.4 µmol in two divided doses (1.2 µmol each). Each dose was prepared as a 30 mL solution for infusion.	
Reporting group title	TPM502 4.8 µmol
Reporting group description:	
Participants in this arm received TPM502 at the total dose of 4.8 µmol in two divided doses (2.4 µmol each). Each dose was prepared as a 30 mL solution for infusion.	
Reporting group title	TPM502 7.2 µmol
Reporting group description:	
Participants randomised to this arm received TPM502 at the total dose of 7.2 µmol in two divided doses (3.6 µmol each). Each dose was prepared as a 30 mL solution for infusion.	
Reporting group title	Placebo
Reporting group description:	
Ferinject solution diluted to 2 mg iron/ml was used as placebo and administered as 30 ml infusion. Ferinject, an iron preparation, was chosen as placebo in this study because of its visual characteristics (i.e., its colour), relevant to maintain the study blinding.	

Primary: TEAE incidence

End point title	TEAE incidence[1]
End point description:	

End point type	Primary
End point timeframe:	
Throughout the study, on average 43 days	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics were used in the evaluation of the safety and tolerability of escalating doses of TPM502 in CeD patients.

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	6	6	6
Units: events	94	58	101	75

End point values	Placebo			

Subject group type	Reporting group			
Number of subjects analysed	12			
Units: events	100			

Statistical analyses

No statistical analyses for this end point

Primary: TEAE causality

End point title	TEAE causality[2]

End point description:

Number of TEAE events assessed to be related to IMP.

End point type	Primary

End point timeframe:

Throughout the study, on average 43 days

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics were used in the evaluation of the safety and tolerability of escalating doses of TPM502 in CeD patients.

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	6	6	6
Units: events	41	32	53	40

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: events	24			

Statistical analyses

No statistical analyses for this end point

Primary: TEAE severity

End point title	TEAE severity[3]

End point description:

All TEAEs, both IMP- and not IMP-related are described.
The one Grade 4 AE was not IMP-related and had onset during the follow-up period of the study.

End point type	Primary

End point timeframe:

Throughout the study, on average 43 days

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics were used in the evaluation of the safety and tolerability of escalating doses of TPM502 in CeD patients.

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	6	6	6
Units: events				
Grade 1	77	51	88	37
Grade 2	17	7	14	29
Grade 3	0	0	0	8
Grade 4	0	0	0	1

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: events				
Grade 1	82			
Grade 2	15			
Grade 3	3			
Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: IL-2 AUC

End point title	IL-2 AUC

End point description:

Change in the log of IL-2 AUC after gluten challenge (GC) post TPM502 treatment (Day 22) versus IL-2 after GC at screening (Day -28).

End point type	Secondary

End point timeframe:

Day 22

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: pg.h/ml				
arithmetic mean (standard deviation)	0.023 (± 0.374)	-0.098 (± 0.151)	-0.258 (± 0.396)	-0.063 (± 0.271)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: pg.h/ml				
arithmetic mean (standard deviation)	0.112 (± 0.485)			

Statistical analyses

No statistical analyses for this end point

Secondary: TPM502 Cmax (Day 1)

End point title	TPM502 Cmax (Day 1)[4]

End point description:

Maximum observed plasma concentration of the peptide components (i.e. TPCs) after dosing.

End point type	Secondary

End point timeframe:

Day 1

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Descriptive statistics were used.

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: ng/ml				
median (full range (min-max))				
TPC0203	12.8 (10.6 to 22.9)	89.4 (47.6 to 116.0)	191.0 (118.0 to 287.0)	418.5 (211.0 to 578.0)
TPC0205	21.5 (13.0 to 49.1)	166.0 (119.0 to 214.0)	304.5 (246.0 to 413.0)	641.0 (246.0 to 800.0)
TPC0206	14.1 (10.5 to 26.3)	106.0 (69.4 to 125.0)	216.0 (177.0 to 320.0)	463.0 (182.0 to 612.0)

Statistical analyses

No statistical analyses for this end point

Secondary: TPM502 Cmax (Day 15)

End point title	TPM502 Cmax (Day 15)[5]

End point description:

Maximum observed plasma concentration of the peptide components (i.e. TPCs) after dosing.

End point type	Secondary

End point timeframe:

Day 15

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Descriptive statistics were used.

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: ng/ml				
median (full range (min-max))				
TPC0203	14.1 (10.4 to 17.6)	81.9 (68.4 to 120.0)	175.0 (114.0 to 347.0)	447.5 (261.0 to 701.0)
TPC0205	16.2 (13.9 to 37.5)	161.0 (147.0 to 212.0)	252.5 (222.0 to 430.0)	653.0 (338.0 to 912.0)
TPC0206	17.4 (10.8 to 21.5)	89.2 (81.2 to 135.0)	89.2 (81.2 to 135.0)	466.5 (269.0 to 582.0)

Statistical analyses

No statistical analyses for this end point

Secondary: TPM502 AUC (0-last) (Day 1)

End point title	TPM502 AUC (0-last) (Day 1)[6]

End point description:

Area under the plasma concentration-time curve from time zero to the time of the last quantifiable PK sample.

End point type	Secondary

End point timeframe:

Day 1

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Descriptive statistics were used.

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: h.ng/ml				
median (full range (min-max))				
TPC0203	3.9 (1.5 to 7.5)	36.4 (17.0 to 49.1)	105.1 (71.6 to 154.7)	231.4 (114.8 to 644.3)

TPC0205	5.9 (1.8 to 24.1)	106.4 (67.0 to 162.8)	257.7 (148.4 to 317.6)	523.0 (265.8 to 901.4)
TPC0206	3.7 (1.1 to 41.2)	350.8 (145.3 to 536.7)	797.0 (726.3 to 1050.0)	1213.3 (587.0 to 2056.7)

Statistical analyses

No statistical analyses for this end point

Secondary: TPM502 AUC (0-last) (Day 15)

End point title	TPM502 AUC (0-last) (Day 15)[7]

End point description:

Area under the plasma concentration-time curve from time zero to the time of the last quantifiable PK sample.

End point type	Secondary

End point timeframe:

Day 15

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Descriptive statistics were used.

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: h.ng/ml				
median (full range (min-max))				
TPC0203	4.3 (1.3 to 5.9)	36.8 (24.2 to 67.5)	99.6 (62.8 to 199.6)	288.8 (113.2 to 746.4)
TPC0205	4.6 (4.2 to 18.0)	120.0 (95.3 to 157.0)	252.8 (143.4 to 293.8)	540.9 (241.9 to 1227.8)
TPC0206	3.8 (1.1 to 6.3)	273.9 (93.3 to 589.5)	273.9 (93.3 to 589.5)	1265.0 (596.3 to 2122.3)

Statistical analyses

No statistical analyses for this end point

Secondary: CeD PRO - COMPGI2

End point title	CeD PRO - COMPGI2

End point description:

COMPGI2 is a composite score including the nausea and vomiting items of the CeD PRO.
Results represent the mean and SD of the change between Day 22 (post treatment gluten challenge) and Day -28 (screening gluten challenge) AUCs (calculated over a period of 6 hours).

End point type	Secondary

End point timeframe:

Day 22

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: unitless score				
arithmetic mean (standard deviation)	0.003 (± 4.41)	-2.04 (± 2.32)	4.87 (± 15.8)	-5.43 (± 10.7)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: unitless score				
arithmetic mean (standard deviation)	5.27 (± 12.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: CeD PRO - COMPGI7

End point title	CeD PRO - COMPGI7

End point description:

COMPGI7 is a composite score including all gastrointestinal symptom items of the CeD PRO.
Results represent the mean and SD of the change between Day 22 (post treatment gluten challenge) and Day -28 (screening gluten challenge) AUCs (calculated over a period of 6 hours).

End point type	Secondary

End point timeframe:

Day 22

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: unitless score				
arithmetic mean (standard deviation)	0.530 (± 15.2)	-8.40 (± 20.4)	-2.84 (± 30.9)	-36.6 (± 35.3)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: unitless score				

arithmetic mean (standard deviation)	11.3 (± 48.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: CeD PRO - COMPGI10

End point title	CeD PRO - COMPGI10

End point description:

COMPGI10 is a composite score including all ten symptom items of the CeD PRO.
Results represent the mean and SD of the change between Day 22 (post treatment gluten challenge) and Day -28 (screening gluten challenge) AUCs (calculated over a period of 6 hours).

End point type	Secondary

End point timeframe:

Day 22

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: unitless score				
arithmetic mean (standard deviation)	-18.1 (± 38.4)	-16.2 (± 34.0)	-15.6 (± 33.4)	-52.1 (± 47.5)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: unitless score				
arithmetic mean (standard deviation)	-1.20 (± 66.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: GloSS PRO

End point title	GloSS PRO

End point description:

Results represent the mean and SD of the change between Day 22 (post treatment gluten challenge) and Day -28 (screening gluten challenge) AUCs (calculated over a period of 6 hours) of the GloSS patient-reported outcome.

End point type	Secondary

End point timeframe:
Day 22

End point values	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol	TPM502 7.2 µmol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: unitless score				
arithmetic mean (standard deviation)	-4.88 (± 7.71)	-0.976 (± 3.83)	-4.11 (± 2.49)	-2.96 (± 11.2)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: unitless score				
arithmetic mean (standard deviation)	2.49 (± 10.1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment emergent adverse events are reported here (from Day -1 to Day 43/end of trial).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	TPM502 0.72 µmol

Reporting group description:

Participants randomised to this arm received TPM502 at the total dose of 0.72 µmol in two divided doses (0.36 µmol each).
Each dose was prepared as a 30 mL solution for infusion.

Reporting group title	TPM502 2.4 µmol

Reporting group description:

Participants randomised to this arm received TPM502 at the total dose of 2.4 µmol in two divided doses (1.2 µmol each).
Each dose was prepared as a 30 mL solution for infusion.

Reporting group title	TPM502 4.8 µmol

Reporting group description:

Participants in this arm received TPM502 at the total dose of 4.8 µmol in two divided doses (2.4 µmol each).
Each dose was prepared as a 30 mL solution for infusion.

Reporting group title	TPM502 7.2 µmol

Reporting group description:

Participants randomised to this arm received TPM502 at the total dose of 7.2 µmol in two divided doses (3.6 µmol each).
Each dose was prepared as a 30 mL solution for infusion.

Reporting group title	Placebo

Reporting group description:

Ferinject solution diluted to 2 mg iron/ml was used as placebo and administered as 30 mL infusion. Ferinject, an iron preparation, was chosen as placebo in this study because of its visual characteristics (i.e., its colour), relevant to maintain the study blinding.

Serious adverse events	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Subdural heamatoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	TPM502 7.2 µmol	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Subdural heamatoma			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	TPM502 0.72 µmol	TPM502 2.4 µmol	TPM502 4.8 µmol
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	6 / 6 (100.00%)	6 / 6 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pallor			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Chills			

subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	3	1	1
Fatigue			
subjects affected / exposed	6 / 8 (75.00%)	2 / 6 (33.33%)	4 / 6 (66.67%)
occurrences (all)	16	7	8
Feeling hot			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Injection site reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Sensation of foreign body			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Thirst			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Hiccups			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Throat irritation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Alcoholic hangover			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Investigations			
Blood fibrinogen increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Complement factor C3 increased			

subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Skin injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	4 / 6 (66.67%)
occurrences (all)	2	0	5
Dysgeusia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Headache			
subjects affected / exposed	3 / 8 (37.50%)	2 / 6 (33.33%)	3 / 6 (50.00%)
occurrences (all)	8	2	7
Paraesthesia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	2	1	2
Presyncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tremor			

subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Eye inflammation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Photopsia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Abdominal distension			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	1	4	5
Abdominal pain			
subjects affected / exposed	3 / 8 (37.50%)	2 / 6 (33.33%)	4 / 6 (66.67%)
occurrences (all)	8	4	9
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	3 / 6 (50.00%)	1 / 6 (16.67%)
occurrences (all)	0	3	1
Constipation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
subjects affected / exposed	5 / 8 (62.50%)	2 / 6 (33.33%)	3 / 6 (50.00%)
occurrences (all)	6	6	9
Faeces hard			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Faeces soft			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	4	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Nausea			
subjects affected / exposed	5 / 8 (62.50%)	5 / 6 (83.33%)	5 / 6 (83.33%)
occurrences (all)	14	8	21
Vomiting			
subjects affected / exposed	6 / 8 (75.00%)	3 / 6 (50.00%)	5 / 6 (83.33%)
occurrences (all)	11	4	13
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dermatitis contact			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Rash			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Micturition urgency			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Musculoskeletal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1

Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Otitis media acute			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2

Non-serious adverse events	TPM502 7.2 µmol	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	12 / 12 (100.00%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Pallor			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Administration site haematoma			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Catheter site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	
occurrences (all)	2	1	

Fatigue			
subjects affected / exposed	3 / 6 (50.00%)	7 / 12 (58.33%)	
occurrences (all)	5	10	
Feeling hot			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Injection site swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Oedema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Sensation of foreign body			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Thirst			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	
occurrences (all)	0	3	
Respiratory, thoracic and mediastinal disorders			

Hiccups			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Nasal congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Throat irritation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Alcoholic hangover			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Depressed mood			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Investigations			
Blood fibrinogen increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Blood pressure systolic decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Body temperature increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
C-reactive protein increased			
subjects affected / exposed	2 / 6 (33.33%)	0 / 12 (0.00%)	
occurrences (all)	3	0	
Complement factor C3 increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Head injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin injury			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Subdural haematoma			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 6 (16.67%)	4 / 12 (33.33%)	
occurrences (all)	1	4	
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	2 / 6 (33.33%)	9 / 12 (75.00%)	
occurrences (all)	3	19	
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Presyncope			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			

Leukocytosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Photopsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	1 / 6 (16.67%)	4 / 12 (33.33%)	
occurrences (all)	2	4	
Abdominal pain			
subjects affected / exposed	3 / 6 (50.00%)	1 / 12 (8.33%)	
occurrences (all)	3	2	
Abdominal pain upper			
subjects affected / exposed	2 / 6 (33.33%)	3 / 12 (25.00%)	
occurrences (all)	4	3	
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	5 / 6 (83.33%)	4 / 12 (33.33%)	
occurrences (all)	6	9	
Faeces hard			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Faeces soft			

subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	2 / 6 (33.33%)	1 / 12 (8.33%)	
occurrences (all)	2	1	
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	5 / 6 (83.33%)	11 / 12 (91.67%)	
occurrences (all)	13	15	
Vomiting			
subjects affected / exposed	5 / 6 (83.33%)	10 / 12 (83.33%)	
occurrences (all)	10	10	
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Dermatitis contact			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	3	
Urticaria			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	
occurrences (all)	2	1	
Renal and urinary disorders			
Micturition urgency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Nasopharyngitis			
subjects affected / exposed	2 / 6 (33.33%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Otitis media acute			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 January 2024	The substantial amendment was implemented to align with current standard of care regarding Covid infection (i.e. full Covid vaccination no longer a requirement), to ensure the eligibility criteria allow inclusion of “average” celiac patients (i.e. qualifying BMI range slightly modified) and to ensure adequate safety and pharmacodynamic monitoring in light of the knowledge acquired to date (CRP measurement introduced at Day 8 and 22). Given the proposed changes (i.e. specifically, the modification of the eligibility criteria, namely the BMI and Covid vaccination requirements), this amendment was regarded as substantial, even though the proposed changes had no impact on the scientific value of the trial nor on the safety monitoring and risk minimization approach of the clinical study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported