



Clinical trial results:

Open label Randomized Controlled clinical Trial of vedolizumab versus conventional treatment for Checkpoint Inhibitor induced Colitis

Summary

EudraCT number	2020-005793-10
Trial protocol	DK
Global end of trial date	30 November 2024

Results information

Result version number	v1 (current)
This version publication date	28 March 2026
First version publication date	28 March 2026

Trial information

Trial identification

Sponsor protocol code	01012121
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04797325
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Copenhagen university hospital Herlev
Sponsor organisation address	Borgmester Ib Juuls vej 1, Herlev, Denmark, 2730
Public contact	Emilie Kristine Dahl, Jakob Benedict Seidelin, 45 35452514, jakob.benedict.seidelin@regionh.dk
Scientific contact	Emilie Kristine Dahl, Jakob Benedict Seidelin, 45 29919696, emilie.kristine.dahl@regionh.dk

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	08 April 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 November 2024
Global end of trial reached?	Yes
Global end of trial date	30 November 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial is to evaluate the safety and efficacy of vedolizumab as a first line treatment of immune check point inhibitor (ICPI) induced colitis.

Protection of trial subjects:

We performed a planned safety analysis after 10 patients had received the trial drug vedolizumab to ensure clinical response.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 November 2021
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	Denmark: 41
Worldwide total number of subjects	41
EEA total number of subjects	41

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)	23
From 65 to 84 years	18
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients were recruited from the out patient clinic and from the ward

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Patients were randomly assigned in a 1:1 ratio using a computer-generated sequence. A research assistant, without involvement in the trial, generated sealed opaque envelopes with the randomization code.

Arms

Are arms mutually exclusive?	Yes
Arm title	Vedolizumab

Arm description: -

Arm type	Experimental
Investigational medicinal product name	vedolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for concentrate for solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Patients receiving vedolizumab 300 mg IV at week 0, 2, 6, 14, 22.

Arm title	Conventional
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Arm description:

Standard treatment with corticosteroids and infliximab rescue treatment at treatment failure to corticosteroids

Arm type	Active comparator
Investigational medicinal product name	corticosteroid
Investigational medicinal product code	
Other name	Prednisolone
Pharmaceutical forms	Tablet, Powder and solvent for dispersion for injection
Routes of administration	Injection , Oral use

Dosage and administration details:

Corticosteroids were administered and tapered accordingly to symptoms.

Number of subjects in period 1	Vedolizumab	Conventionel
Started	22	19
Completed	20	18
Not completed	2	1
Lost to follow-up	2	1

Baseline characteristics

Reporting groups

Reporting group title	Vedolizumab
Reporting group description: -	
Reporting group title	Conventionel
Reporting group description:	
Standard treatment with corticosteroids and infliximab rescue treatment at treatment failure to corticosteroids	

Reporting group values	Vedolizumab	Conventionel	Total
Number of subjects	22	19	41
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	13	11	24
From 65-84 years	9	8	17
85 years and over	0	0	0
adults	0	0	0
Gender categorical			
Units: Subjects			
Female	7	5	12
Male	15	14	29

End points

End points reporting groups

Reporting group title	Vedolizumab
Reporting group description:	-
Reporting group title	Conventional
Reporting group description:	Standard treatment with corticosteroids and infliximab rescue treatment at treatment failure to corticosteroids

Primary: cumulative dose of corticosteroids at week 30

End point title	cumulative dose of corticosteroids at week 30
End point description:	cumulative dose of corticosteroids at week 30
End point type	Primary
End point timeframe:	From randomisation to week 30

End point values	Vedolizumab	Conventional		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	18		
Units: mg				
arithmetic mean (standard deviation)	1378 (± 447)	2390 (± 384)		

Statistical analyses

Statistical analysis title	primary outcome
Comparison groups	Vedolizumab v Conventional
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	equivalence ^[1]
P-value	= 0.107 ^[2]
Method	welch's t-test

Notes:

[1] - We will use the 30-weeks survivors analysis set. Missing data for the patient(s) lost to follow-up will be imputed and transparently reported. Because of the small sample size, the main analysis will consist of a simple unadjusted analysis a Welch's t-test analysis. The empirical (i.e. observed) means in each group and their difference will be reported, together with the corresponding 95% two-sided confidence intervals.

[2] - A two sided p-value for the null of hypothesis of no difference in mean will be reported. That is, the standard output of the call to the t.test() function of R will be reported.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Each patient had adverse events registered from entering the trial at randomisation and until the trial period ended 30 weeks later.

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
Dictionary version	5

Reporting groups

Reporting group title	vedolizumab
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Reporting group description:

patients in the vedolizumab arm

Reporting group title	conventionel
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Reporting group description: -

Serious adverse events	vedolizumab	conventionel	
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 22 (59.09%)	11 / 19 (57.89%)	
number of deaths (all causes)	1	1	
number of deaths resulting from adverse events	0	0	
Surgical and medical procedures			
bone fracture			
subjects affected / exposed	0 / 22 (0.00%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
planned cancer operation			
subjects affected / exposed	1 / 22 (4.55%)	2 / 19 (10.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pain			
subjects affected / exposed	1 / 22 (4.55%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
electrolyte disturbance			

subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vitamin insufficiency			
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
depression			
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dehydration			
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
anaphylaxis			
subjects affected / exposed	1 / 22 (4.55%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

Diarrhea	Additional description: diarrhea		
subjects affected / exposed	7 / 22 (31.82%)	7 / 19 (36.84%)	
occurrences causally related to treatment / all	0 / 7	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal bleeding			
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nausea			
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
obstipation			
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal perforation	Additional description: at index endoscopy		
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
nephritis			
subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
muscle pain			

subjects affected / exposed	1 / 22 (4.55%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
infections			
subjects affected / exposed	2 / 22 (9.09%)	8 / 19 (42.11%)	
occurrences causally related to treatment / all	1 / 2	3 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	vedolizumab	conventionel	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 22 (100.00%)	19 / 19 (100.00%)	
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 22 (31.82%)	8 / 19 (42.11%)	
occurrences (all)	7	8	
General disorders and administration site conditions			
Dizziness			
subjects affected / exposed	3 / 22 (13.64%)	5 / 19 (26.32%)	
occurrences (all)	3	5	
Performance status decreased			
subjects affected / exposed	6 / 22 (27.27%)	7 / 19 (36.84%)	
occurrences (all)	6	7	
Fatigue			
subjects affected / exposed	6 / 22 (27.27%)	7 / 19 (36.84%)	
occurrences (all)	6	7	
hyperactive bladder			
subjects affected / exposed	1 / 22 (4.55%)	3 / 19 (15.79%)	
occurrences (all)	1	3	
Insomnia			
subjects affected / exposed	0 / 22 (0.00%)	3 / 19 (15.79%)	
occurrences (all)	0	3	
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	7 / 22 (31.82%)	4 / 19 (21.05%)	
occurrences (all)	7	4	
bruises			
subjects affected / exposed	1 / 22 (4.55%)	5 / 19 (26.32%)	
occurrences (all)	1	5	
Eye disorders			
visual sharpness decreased			
subjects affected / exposed	5 / 22 (22.73%)	4 / 19 (21.05%)	
occurrences (all)	5	4	
dry eyes			
subjects affected / exposed	3 / 22 (13.64%)	1 / 19 (5.26%)	
occurrences (all)	3	1	
Gastrointestinal disorders			
Nausea	Additional description: x		
subjects affected / exposed	6 / 22 (27.27%)	5 / 19 (26.32%)	
occurrences (all)	6	5	
obstipation			
subjects affected / exposed	5 / 22 (22.73%)	5 / 19 (26.32%)	
occurrences (all)	5	5	
electrolyte disturbance			
subjects affected / exposed	5 / 22 (22.73%)	4 / 19 (21.05%)	
occurrences (all)	5	4	
vitamin insufficiency	Additional description: x		
subjects affected / exposed	5 / 22 (22.73%)	2 / 19 (10.53%)	
occurrences (all)	5	2	
oral mucositis			
subjects affected / exposed	6 / 22 (27.27%)	8 / 19 (42.11%)	
occurrences (all)	6	8	
vomiting			
subjects affected / exposed	4 / 22 (18.18%)	1 / 19 (5.26%)	
occurrences (all)	4	1	
Dry mouth			
subjects affected / exposed	3 / 22 (13.64%)	1 / 19 (5.26%)	
occurrences (all)	3	1	
stomach pain			

subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2	4 / 19 (21.05%) 4	
Pancreatitis subjects affected / exposed occurrences (all)	1 / 22 (4.55%) 1	4 / 19 (21.05%) 4	
anal pain subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0	2 / 19 (10.53%) 2	
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	6 / 22 (27.27%) 6	7 / 19 (36.84%) 7	
Hepatobiliary disorders Hepatitis subjects affected / exposed occurrences (all)	5 / 22 (22.73%) 5	5 / 19 (26.32%) 5	
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2	6 / 19 (31.58%) 6	
sensory disturbance subjects affected / exposed occurrences (all)	1 / 22 (4.55%) 1	2 / 19 (10.53%) 2	
vitiligo subjects affected / exposed occurrences (all)	1 / 22 (4.55%) 1	2 / 19 (10.53%) 2	
moon face subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0	2 / 19 (10.53%) 2	
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2	2 / 19 (10.53%) 2	
Osteoporosis subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0	2 / 19 (10.53%) 2	

Musculoskeletal and connective tissue disorders			
muscle pain	Additional description: x		
subjects affected / exposed	4 / 22 (18.18%)	10 / 19 (52.63%)	
occurrences (all)	4	10	
joint pain			
subjects affected / exposed	7 / 22 (31.82%)	4 / 19 (21.05%)	
occurrences (all)	7	4	
puritus			
subjects affected / exposed	7 / 22 (31.82%)	1 / 19 (5.26%)	
occurrences (all)	7	1	
periferal odema			
subjects affected / exposed	3 / 22 (13.64%)	5 / 19 (26.32%)	
occurrences (all)	3	5	
Infections and infestations			
infections	Additional description: x		
subjects affected / exposed	10 / 22 (45.45%)	8 / 19 (42.11%)	
occurrences (all)	16	14	
fever without infection			
subjects affected / exposed	3 / 22 (13.64%)	1 / 19 (5.26%)	
occurrences (all)	3	1	
Metabolism and nutrition disorders			
nefritis			
subjects affected / exposed	2 / 22 (9.09%)	0 / 19 (0.00%)	
occurrences (all)	2	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 January 2022	Change of inclusion and exclusion criteria. We broaden the inclusion criteria to also include hospitalized patients.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported