Clinical trial results:
Unilateral, open and randomized phase IV study of 2 groups to assess the degree of comfort with simple Emuliquen® in patients undergoing proctological surgery

Summary

EudraCT number	2017-002811-33
Trial protocol	ES
Global end of trial date	20 April 2021

Results information

Result version number	v1 (current)
This version publication date	23 July 2022
First version publication date	23 July 2022
Summary attachment (see zip file)	RESUMEN DE RESULTADOS_LAINCO1107 (Resumen de resultados_LAINCO1107.pdf)

Trial information

Trial identification

Sponsor protocol code	LAINCO1107

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	LAINCO S.A.
Sponsor organisation address	Avda. Bizet 8-12 , Rubí, Barcelona, Spain,
Public contact	Anna Royo, Dynamic, 0034 933511615, a.royo@evidenze.com
Scientific contact	Anna Royo, Dynamic, 0034 933511615, a.royo@evidenze.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	20 October 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 April 2021
Global end of trial reached?	Yes
Global end of trial date	20 April 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the degree of comfort that patients experience after undergoing proctological surgery

Protection of trial subjects:

Study performed folowing good clinical practices and royal decree 190/2015

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 December 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 110
Worldwide total number of subjects	110
EEA total number of subjects	110

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)	93
From 65 to 84 years	17
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening of 21 days where inclusion criteria are confirmed. It coincides with the pre-operative period.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Emuliquen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral emulsion
Routes of administration	Oral use

Dosage and administration details:

500mg/ml every day at least 4 weeks and a maximum of 5 weeks.

Arm title	Group B

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Lactulosa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

10gr every day for at least 4 weeks and a maximum of 5 weeks.

Number of subjects in period 1	Group A	Group B
Started	56	54
Completed	49	41
Not completed	7	13
Consent withdrawn by subject	4	5
Adverse event, non-fatal	-	2
Pregnancy	-	1
Lost to follow-up	3	5

Baseline characteristics

Reporting groups	
Reporting group title	Group A
Reporting group description: -	
Reporting group title	Group B
Reporting group description: -	

Reporting group values	Group A	Group B	Total
Number of subjects	56	54	110
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	47.3	51.6	
standard deviation	± 12.6	± 12.9	-
Gender categorical Units: Subjects			
Female	22	19	41
Male	34	35	69

End points

End points reporting groups

Reporting group title	Group A
Reporting group description: -	
Reporting group title	Group B
Reporting group description: -	

Primary: intestinal colic episodes

End point title	intestinal colic episodes
End point description:	
The results are presented as number of patients with at least one intestinal colic during all the study.	
End point type	Primary
End point timeframe:	
All the study, since the first dose until the end of the treatment.	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37[1]	26[2]		
Units: Number of patients				
YES	23	14		
NO	14	12		

Notes:

[1] - Per protocol population

[2] - Per protocol population

Statistical analyses

Statistical analysis title	Chi squared
Comparison groups	Group A v Group B
Number of subjects included in analysis	63
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.509 [3]
Method	Chi-squared

Notes:

[3] - Statistically non-significant

Primary: flatulence episodes

End point title	flatulence episodes
End point description:	
The results are presented as number of patients with at least one intestinal colic	
End point type	Primary
End point timeframe:	
All the study, since the first dose until the end of the treatment.	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	27		
Units: Number of patients				
YES	36	27		
NO	1	0		

Statistical analyses

Statistical analysis title	Fisher
Comparison groups	Group A v Group B
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999 [4]
Method	Fisher exact

Notes:

[4] - statistically non-significant

Secondary: degree of effort during defecation

End point title	degree of effort during defecation

End point description:

The results are presented as number of patients with at least one intestinal colic during all the study.

End point type	Secondary

End point timeframe:

All the study, since the first dose until the end of the treatment.

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37[5]	27[6]		
Units: Patients				
YES	33	25		
NO	4	2		

Notes:

[5] - Per protocol population

[6] - Per protocol population

Statistical analyses

Statistical analysis title	Fisher
Comparison groups	Group B v Group A

Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999
Method	Fisher exact

Secondary: degree of pain during defecation

End point title	degree of pain during defecation

End point description:

End point type	Secondary

End point timeframe:

All the study, since the first dose until the end of the treatment.

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37[7]	27[8]		
Units: EVA scale				
arithmetic mean (standard deviation)	3.4 (± 2.4)	3.1 (± 2.0)		

Notes:

[7] - per protocol population

[8] - per protocol population

Statistical analyses

No statistical analyses for this end point

Secondary: episodes of diarrhoea

End point title	episodes of diarrhoea

End point description:

The results are presented as number of patients with at least one diarrhea episode during all the study.

End point type	Secondary

End point timeframe:

All the study, since the first dose until the end of the treatment.

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	27		
Units: Patients				
YES	23	14		
NO	13	13		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Since signature of informed consent until the last visit of the study.	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.1
Reporting groups	
Reporting group title	Safety population (group A)
Reporting group description: -	
Reporting group title	Safety population (group B)
Reporting group description: -	

Serious adverse events	Safety population (group A)	Safety population (group B)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 56 (0.00%)	0 / 54 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Safety population (group A)	Safety population (group B)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 56 (0.00%)	3 / 54 (5.56%)	
Gastrointestinal disorders			
Diarrhea			
subjects affected / exposed	0 / 56 (0.00%)	2 / 54 (3.70%)	
occurrences (all)	0	2	
Pain after defecation			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported