



Clinical trial results:

EFICACY AND TOLERABILITY OF TWO REDUCED VOLUME PRODUCTS FOR COLORRECTAL CANCER SCREENING COLONOSCOPY: A COMPARATIVE, PARALLEL RANDOMIZED CLINICAL TRIAL. LOWOL STUDY.

Summary

EudraCT number	2019-003186-18
Trial protocol	ES
Global end of trial date	11 November 2022

Results information

Result version number	v1 (current)
This version publication date	11 June 2026
First version publication date	11 June 2026

Trial information

Trial identification

Sponsor protocol code	LOWOL-19
-----------------------	----------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04297423
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundació Clínic per a la Recerca Biomèdica
Sponsor organisation address	C/ Villarroel 170, Barcelona, Spain,
Public contact	Joan Albert Arnaiz, CTU CLINIC, 34 932279838, jaarnaiz@clinic.cat
Scientific contact	Joan Albert Arnaiz, CTU CLINIC, 34 932279838, jaarnaiz@clinic.cat

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 November 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 November 2022
Global end of trial reached?	Yes
Global end of trial date	11 November 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Compare the clinical efficacy between two products in individuals who will undergo a colonoscopy in a CCR screening program.

Protection of trial subjects:

The study was conducted in accordance with the Declaration of Helsinki, ICH-GCP E6(R2) guidelines, EU Regulation 536/2014, and Spanish Royal Decree 1090/2015. The protocol was approved by the Ethics Committee for Research with Medicinal Products (CEIm) and authorized by the Spanish Agency of Medicines and Medical Devices (AEMPS). All participants provided written informed consent before enrolment. Subject confidentiality and data protection were ensured throughout the study. Safety monitoring included the collection and assessment of adverse events during trial participation.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 March 2020
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: 1002
Worldwide total number of subjects	1002
EEA total number of subjects	1002

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)	739
From 65 to 84 years	263

85 years and over	0
-------------------	---

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 1236 subjects were assessed for eligibility, of whom 1002 met inclusion criteria, provided informed consent, and were enrolled and randomized. No pre-assignment period was applied, and all exclusions occurred after randomization.

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:

The endoscopist (outcome assessor) was blinded to treatment allocation.

Arms

Are arms mutually exclusive?	Yes
Arm title	1 L PEGA group

Arm description:

1 L Polyethylene glycol plus ascorbate

Arm type	Experimental
Investigational medicinal product name	Polyethylene glycol 3350 plus ascorbate
Investigational medicinal product code	
Other name	Polyethylene glycol plus ascorbate, PEG 3350 + ascorbate, 1L-PEGA, Pleinvue
Pharmaceutical forms	Powder for oral solution
Routes of administration	Oral use

Dosage and administration details:

Split-dose bowel preparation regimen:

First dose: administered the evening before colonoscopy (20:00), consisting of polyethylene glycol 3350 with electrolytes dissolved in 500 mL water, ingested at approximately 250 mL every 15 minutes, followed by at least 500 mL of clear liquids.

Second dose: administered approximately 4 hours before colonoscopy, consisting of polyethylene glycol 3350 plus ascorbate (two sachets) dissolved in 500 mL water, followed by at least 500 mL of clear liquids.

Conducted under a low-residue diet for 2 days prior and liquid diet from the afternoon before the procedure.

Arm title	SPMc group
------------------	------------

Arm description:

Sodium picosulfate with magnesium citrate

Arm type	Active comparator
Investigational medicinal product name	Sodium picosulfate with magnesium citrate
Investigational medicinal product code	
Other name	Sodium picosulfate + magnesium citrate, SPMC, CitraFleet
Pharmaceutical forms	Powder for oral solution
Routes of administration	Oral use

Dosage and administration details:

Split-dose bowel preparation regimen:

First dose: administered the evening before colonoscopy (20:00), consisting of sodium picosulfate with magnesium citrate dissolved in approximately 250 mL of cold water.

After intake, participants must drink at least 1.5 L of clear liquids (e.g. isotonic drinks, strained broth, or water, but not exclusively water).

Second dose: administered approximately 4 hours before colonoscopy, identical to the first dose. Conducted under a low-residue diet for 2 days prior and liquid diet from the afternoon before the procedure.

Number of subjects in period 1	1 L PEGA group	SPMc group
Started	501	501
Completed	450	478
Not completed	51	23
Consent withdrawn by subject	1	-
Physician decision	1	3
Adverse event, non-fatal	-	3
Lost to follow-up	4	11
Protocol deviation	45	6

Baseline characteristics

Reporting groups

Reporting group title	1 L PEGA group
-----------------------	----------------

Reporting group description:

1 L Polyethylene glycol plus ascorbate

Reporting group title	SPMc group
-----------------------	------------

Reporting group description:

Sodium picosulfate with magnesium citrate

Reporting group values	1 L PEGA group	SPMc group	Total
Number of subjects	501	501	1002
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			
median	60	60	
inter-quartile range (Q1-Q3)	55 to 65	55 to 65	-
Gender categorical Units: Subjects			
Female	239	232	471
Male	262	269	531

End points

End points reporting groups

Reporting group title	1 L PEGA group
Reporting group description: 1 L Polyethylene glycol plus ascorbate	
Reporting group title	SPMc group
Reporting group description: Sodium picosulfate with magnesium citrate	

Primary: Percentage of ADR

End point title	Percentage of ADR
End point description: ADR (adenoma detection rate): % of patients with ≥ 1 adenoma	
End point type	Primary
End point timeframe: At the time of colonoscopy (single procedure)	

End point values	1 L PEGA group	SPMc group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	501	501		
Units: Number of subjects				
≥ 1 adenoma detected	269	283		
No adenoma detected	232	218		

Statistical analyses

Statistical analysis title	Primary analysis of adenoma detection rate (ADR)
Statistical analysis description: The primary endpoint (adenoma detection rate, ADR) was analyzed as a proportion and compared between treatment groups. The difference in ADR and its two-sided 95% confidence interval were calculated. Non-inferiority was concluded if the lower limit of the confidence interval was above -10% .	
Comparison groups	1 L PEGA group v SPMc group
Number of subjects included in analysis	1002
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[1]
P-value	< 0.05
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	2.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	9
Variability estimate	Standard error of the mean
Dispersion value	0

Notes:

[1] - Non-inferiority analysis based on difference in proportions with a predefined margin of –10%.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of bowel preparation until 15 days after colonoscopy.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	Not specified
-----------------	---------------

Dictionary version	1.0
--------------------	-----

Reporting groups

Reporting group title	1 L PEGA group
-----------------------	----------------

Reporting group description:

1 L Polyethylene glycol plus ascorbate

Reporting group title	SPMc group
-----------------------	------------

Reporting group description:

Sodium picosulfate with magnesium citrate

Serious adverse events	1 L PEGA group	SPMc group	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 501 (0.20%)	0 / 501 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
Syncope	Additional description: Dizziness and syncope with fall		
subjects affected / exposed	1 / 501 (0.20%)	0 / 501 (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: 5 %

Non-serious adverse events	1 L PEGA group	SPMc group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	486 / 501 (97.01%)	476 / 501 (95.01%)	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	486 / 501 (97.01%)	476 / 501 (95.01%)	
occurrences (all)	486	476	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 June 2020	Protocol amendment version 3.0, date 15-Jun-2020

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Adverse events were collected via questionnaire without standardized coding, which may introduce reporting bias. The study was not powered for safety analysis.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/39069266>