Clinical trial results:
Conditioned Autologous Serum Therapy (Orthokine) on the dorsal root ganglion in patients with chronic radiculalgia (RADISAC)

Summary

EudraCT number	2021-005124-38
Trial protocol	ES
Global end of trial date	30 January 2025

Results information

Result version number	v1 (current)
This version publication date	29 March 2025
First version publication date	29 March 2025

Trial information

Trial identification

Sponsor protocol code	RADISAC

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	DARYD
Sponsor organisation address	Sabino Arana 38, Barcelona, Spain,
Public contact	DARYD, DARYD, martahoms7@gmail.com
Scientific contact	DARYD, DARYD, martahoms7@gmail.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	07 March 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 January 2025
Global end of trial reached?	Yes
Global end of trial date	30 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess whether therapy with conditioned autologous serum on the dorsal root ganglion reduces neuropathic pain in patients with persistent lower limb radiculalgia

Protection of trial subjects:

The principal investigator was the contact person for the patients, who made the first visit, the procedures and the 30-day, 3-month, 6-month and 12-month follow-ups. Nevertheless, the patients had a Pain Unit telephone number and an email at their disposal to contact the principal investigator whenever they needed to.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 November 2021
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Ethical reason, Scientific research
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 70
Worldwide total number of subjects	70
EEA total number of subjects	70

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)	46
From 65 to 84 years	24

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	70
Number of subjects completed	70

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Experimental group

Arm description:

Treatment aply: Puulse Radiofrecuency + Autologus Conditioned Serum

Arm type	Experimental
Investigational medicinal product name	Authologus Conditioned Serum
Investigational medicinal product code	PS-8229-2010
Other name	Authologus conditioned Serum (Orthokine)
Pharmaceutical forms	Injection, Solution for infusion in pre-filled syringe, Solution for injection/infusion in pre-filled syringe
Routes of administration	Infiltration

Dosage and administration details:

4mL

Arm title	Control Group

Arm description:

Treatment aply: Puulse Radiofrecuency + 0'9% Saline Serum

Arm type	Placebo
Investigational medicinal product name	Serum Saline
Investigational medicinal product code	
Other name	0'9% serum saline
Pharmaceutical forms	Solution for infusion, Solution for injection
Routes of administration	Infiltration

Dosage and administration details:

4mL

Number of subjects in period 1	Experimental group	Control Group
Started	35	35
Completed	35	35

Baseline characteristics

End points

End points reporting groups

Reporting group title	Experimental group
Reporting group description:	
Treatment aply: Puulse Radiofrecuency + Autologus Conditioned Serum	
Reporting group title	Control Group
Reporting group description:	
Treatment aply: Puulse Radiofrecuency + 0'9% Saline Serum	
Subject analysis set title	Control group
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All patiets included in study recived RDF therapy on the DRG for 8 minutes (45 V) of the root affects. At the end of the RFP therapy, a 3mL dose of autologus serum therapy (AST, Orthokine) will be administered on the DRG in patients of exeprimental group; and a 3mL dose of 0.9% physiological saline in patients in the contol group	
Subject analysis set title	Experimental group
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All patiets included in study recived RDF therapy on the DRG for 8 minutes, (45 V) of the root affects. At the end of the RFP therapy, a 3mL dose of autologus serum therapy (AST, Orthokine) will be administered on the DRG in patients of exeprimental group; and a 3mL dose of 0.9% physiological saline in patients in the control group	

Primary: Level of Pain (VSG)

End point title	Level of Pain (VSG)
End point description:	
End point type	Primary
End point timeframe:	
30 days / 3 months / 6 months /12 months	

End point values	Control group	Experimental group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	35		
Units: scale of pain (0-10)				
arithmetic mean (standard deviation)	6.64 (± 2.37)	3.16 (± 2.02)		

Statistical analyses

Statistical analysis title	Mixed linear model
Statistical analysis description:	
To determine the evolution for each of the variables during the 4 follow-up visits (30 days, 3 months, 6 months and 12 months), a mixed model for repeated measures or a generalized linear model for repeated measures will be carried out, as appropriate. All analyzes will be carried out by intention to treat (ITT)	
Comparison groups	Experimental group v Control group

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05 [1]
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Confidence interval	
sides	2-sided
Variability estimate	Standard deviation

Notes:

[1] - significant p value < 0.05

Secondary: Neuropathic pain	
End point title	Neuropathic pain

End point description:

End point type	Secondary

End point timeframe:

30 days/ 3 months/ 6 months / 12 months

End point values	Experimental group	Control Group	Control group	Experimental group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	35	35	35	35
Units: DN4 (0-10)				
arithmetic mean (standard deviation)	5.15 (± 1.73)	5.17 (± 2.49)	3.61 (± 2.43)	4.39 (± 2.25)

Statistical analyses

Statistical analysis title	Mixed linear model
Comparison groups	Control group v Experimental group
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05 [2]
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Variability estimate	Standard deviation

Notes:

[2] - Significant p< 0.05

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Throughout the period in which patients received treatment and subsequent follow-up visits, both complications and adverse effects were recorded.

Adverse event reporting additional description:

Additionally, apart from the scheduled visits at 30 days, 3 months, 6 months, and 12 months, patients had direct access to a phone line for the unit, allowing them to contact the principal investigator in case they experienced any adverse effects.

Assessment type	Non-systematic

Dictionary used

Dictionary name	SEFV-H: SISTEMA ESPA
Dictionary version	1

Reporting groups

Reporting group title	Adverse events Experimental Group

Reporting group description:

Patients of the Experimental Group who experienced adverse effects.

Reporting group title	Adverse events control group

Reporting group description:

Patients of the control group who experienced adverse effects.

Serious adverse events	Adverse events Experimental Group	Adverse events control group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0.02 %

Non-serious adverse events	Adverse events Experimental Group	Adverse events control group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: There were no no-serious adverse events.

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

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

At the 12-month follow-up, a lower number of patients were observed during the analysis, as some of them, due to persistent symptoms, preferred to pursue other types of treatment and were therefore excluded from the final analysis.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/38007491