Clinical trial results:
Clinical Trial to determine efficacy and safety of healing with platelet-rich plasma, fibrin and leukocytes compared to standard healing with nitrofurazone ointment in subjects with onychocryptosis.

Summary

EudraCT number	2016-002048-18
Trial protocol	ES
Global end of trial date	30 May 2019

Results information

Result version number	v1 (current)
This version publication date	18 November 2021
First version publication date	18 November 2021
Summary attachment (see zip file)	RESULTADOS (Informe final de resultados del ensayo.pdf)

Trial information

Trial identification

Sponsor protocol code	16/195

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	XAVIER GARRIDO CASTELLS
Sponsor organisation address	Plaza España, 14-1, Canals, Spain, 46650
Public contact	XAVIER GARRIDO CASTELLS, XAVIER GARRIDO CASTELLS, 34 661451622, xavi3garrido@hotmail.com
Scientific contact	XAVIER GARRIDO CASTELLS, XAVIER GARRIDO CASTELLS, 34 661451622, xavi3garrido@hotmail.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	15 May 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 May 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

DETERMINING THE IMPROVEMENT OF POSTOPERATIVE PROCESS WITH HEALING WITH LEUCOCYTES, FIBRINE AND PLATELETS RICH PLASMA CLOT IN COMPARISON WITH THE STANDARD HEALING WITH NITROFURAZONE OINTMENT.

Protection of trial subjects:

All subjects was free of diseases and all signed a informated consentiment.

Background therapy:

All patients results with a satisfactory ended for the resolutions of their problem.

Evidence for comparator:

The LPRF obtaining in general conclusion, a improvement in the days of healing respect the standrad healing. This days was around 7 days less with aplications of LPRF.

Actual start date of recruitment	16 May 2016
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: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	40
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The recruitment of patients was carried out as cases were presented in the clinic, taking into account all the elements determined for the selection.

Pre-assignment

Screening details:

Onichocryptosis stage I and IIa.

Period 1

Period 1 title	All study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	LPRF Patiens

Arm description:

Patients withs aplications postsurgical of LPRF

Arm type	Experimental
Investigational medicinal product name	Leucocyte and Platelet rich firbin
Investigational medicinal product code	
Other name	Leucocyte and Platelet rich firbin
Pharmaceutical forms	Blood fraction modifier
Routes of administration	Epicutaneous use , External use

Dosage and administration details:

5 ml of blood are necesary to building ths clot of LPRF

Arm title	Patients with standard healing

Arm description:

Patients with the aplication of nitrofurazone cream to healing the surgical wound

Arm type	Active comparator
Investigational medicinal product name	Nitrofurazone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Epicutaneous use , External use

Dosage and administration details:

A gauze with 2 ml approximately were applied

Number of subjects in period 1	LPRF Patiens	Patients with standard healing
Started	20	20
Completed	20	20

Baseline characteristics

Reporting groups

Reporting group title	All study

Reporting group description:

The socio-demographic baseline characteristics (sex, age, weight, height, and body mass index (BMI)) of patients were collected by the same physician who performed the chemical matrixectomy surgery with 88% phenol in a sterile manner according to the protocol of Becerro-de-Bengoa-Vallejo et al. [9]. After the surgery, the hallux was washed with a bristled sterile brush and dual-sided foam saturated with povidone iodine for approximately 5 min.
Next, the toenail was wiped clean with sterile gauze and disinfected with 10% povidone-iodine. Subsequently, 2 mL of 2% mepivacaine (without vasoconstrictor) as a local anesthetic was injected. Next, a digital tourniquet was laid at the base of the hallux of the foot. In addition, the nail plate spicule was retrieved at each border (medial and lateral) with a Kelly hemostat. Residual blood in the zone was cleaned with a sterile gauze and then three rounds were applied with a phenol solution for 1 min at each border of the toenail with the termi

Reporting group values	All study	Total	
Number of subjects	40	40	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	40	40	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
median	45.55		
standard deviation	± 12.9	-	
Gender categorical Units: Subjects			
Female	32	32	
Male	8	8	

Subject analysis sets

Subject analysis set title	All Analysis
Subject analysis set type	Full analysis

Subject analysis set description:

The primary outcome measurement was post-surgical bleeding, which was categorized as mild (the dressing did not show external spots; only the polypropylene of the dressing was in contact with the wound, and the gauze was in contact with the dressing), moderate (the dressing might have shown slight spots on the back or sides; the non-adherent dressing might have been completely stained and the gauze in contact with it may have been partially stained), or heavy bleeding (the external bandage could be completely or almost completely colored) [17]. The secondary outcome measurements were post-surgical pain intensity as assessed by the visual analogue scale (VAS, showing an intraclass correlation coefficient of 0.97) on the first, second, and third days after surgery [18], post-surgical

Reporting group values	All Analysis		
Number of subjects	40		
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)	40		
From 65-84 years	0		
85 years and over	0		
Age continuous Units: years			
median	45.55		
standard deviation	± 12.9		
Gender categorical Units: Subjects			
Female	32		
Male	8		

End points

End points reporting groups

Reporting group title	LPRF Patiens
Reporting group description:	
Patients withs aplications postsurgical of LPRF	
Reporting group title	Patients with standard healing
Reporting group description:	
Patients with the aplication of nitrofurazone cream to healing the surgical wound	
Subject analysis set title	All Analysis
Subject analysis set type	Full analysis
Subject analysis set description:	
The primary outcome measurement was post-surgical bleeding, which was categorized as mild (the dressing did not show external spots; only the polypropylene of the dressing was in contact with the wound, and the gauze was in contact with the dressing), moderate (the dressing might have shown slight spots on the back or sides; the non-adherent dressing might have been completely stained and the gauze in contact with it may have been partially stained), or heavy bleeding (the external bandage could be completely or almost completely colored) [17]. The secondary outcome measurements were post-surgical pain intensity as assessed by the visual analogue scale (VAS, showing an intraclass correlation coefficient of 0.97) on the first, second, and third days after surgery [18], post-surgical inflammation as measured by the digital circumference in mm using a flexible ruler (Devon Industries 1-800, Inc., Devon, PA, USA) at the level of the proximal nail fold before and 48 h after surgery during	

Primary: Days of healing

End point title	Days of healing
End point description:	
End point type	Primary
End point timeframe:	
The days of healing were from the day of the intervention until the healing criteria were met.	

End point values	LPRF Patiens	Patients with standard healing		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20[1]	20[2]		
Units: day				
number (not applicable)	20	20		

Notes:

[1] - ONE OF THE HALLUCIS OF OURS PATIENTS

[2] - ONE OF THE HALLUX OF OUR PATIENTS

Statistical analyses

Statistical analysis title	FINAL ANALYSIS
Statistical analysis description:	
WAS THE ANALYSIS OF THE DAYS FOR COMPLET THE HEALING IN BOTH GRUPS	
Comparison groups	LPRF Patiens v Patients with standard healing

Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
lower limit	5
upper limit	95
Variability estimate	Standard error of the mean
Dispersion value	5

Statistical analysis title	FINAL ANALYSIS
Statistical analysis description:	
WAS THE ANALYSIS OF THE DAYS FOR COMPLET THE HEALING IN BOTH GRUPS	
Comparison groups	LPRF Patiens v Patients with standard healing
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
lower limit	5
upper limit	95
Variability estimate	Standard error of the mean
Dispersion value	5

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
No report any case of adverse events	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10.0

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

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: THE INFLAMMATION HAPPEN IN SOME PATIENT FOR THE APPLICATION OF PHENOL, BUT IT IS A NORMAL REACCTION IN THIS TECHNIQUE.

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.

the limitations of our study were in the only one location to select our subjects to study, nothing more limitations.

Notes: