Clinical trial results:
Randomised controlled clinical trial to evaluate the efficacy of a sodium salicylate hydroglyceric solution used at different concentrations in the aesthetic and functional sclerotherapy of veins, venulae and ecstatic capillaries.

Summary

EudraCT number	2004-005147-10
Trial protocol	IT
Global end of trial date	25 May 2006

Results information

Result version number	v1 (current)
This version publication date	22 June 2022
First version publication date	22 June 2022
Summary attachment (see zip file)	study final report (CON-0204-Report clinico.pdf)

Trial information

Trial identification

Sponsor protocol code	KORPO - 0104

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	KORPO s.r.l.
Sponsor organisation address	Via XX settembre 5/28, Genova, Italy, I-16121
Public contact	Sergio Capurro, Korpo s.r.l., 0039 3394303430, info@korpo.com
Scientific contact	Sergio Capurro, Korpo s.r.l., 0039 3394303430, info@korpo.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	12 April 2007
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 May 2006
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of a sodium salicylate hydroglyceric solution experimental name Bisclero used at different concentrations 6 and 10 in the aesthetic and functional sclerotherapy of veins, venulae and ecstatic capillaries by comparing the effects with those of a placebo solution of Ringer lactate.

Protection of trial subjects:

Evaluation of tolerability through registration of all ADRs. In case of problem of tolerability, the treatment should be interrupted

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 March 2006
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	Italy: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	51
From 65 to 84 years	9
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

60 patients of both sexes with bilateral lower-limb pathology, i.e. telangiectasias (diameter of ectasic capillaries not exceeding 1 mm, 30 subjects) or reticular veins (diameter of ectasic capillaries between 1 and 8 mm, 30 subjects) aged between 18 and 75 years, light phototype.

Pre-assignment

Screening details:

For the assessment of tolerability, all adverse events (serious and non-serious) observed during treatment and reported directly by the subject or noted by the investigator were recorded, recording for each of them. In the event of lack of tolerability, treatment would be discontinued

Period 1

Period 1 title	15 days evaluation (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

NA

Arms

Are arms mutually exclusive?	Yes
Arm title	Group Bisclero 6%

Arm description:

Subject with diameter of ectasic capillary 1-8 mm

Arm type	Active comparator
Investigational medicinal product name	Bisclero 6%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravascular use , Intravenous use

Dosage and administration details:

Buffered 6% sodium salicylate hydroglyceric solution for peripheral intravenous use

Arm title	Group Bisclero 10%

Arm description:

Subject with diameter of ectasic capillary < 1 mm

Arm type	Active comparator
Investigational medicinal product name	Bisclero 10%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravascular use , Intravenous use

Dosage and administration details:

Buffered 10% sodium salicylate hydroglyceric solution for peripheral intravenous use

Number of subjects in period 1	Group Bisclero 6%	Group Bisclero 10%
Started	30	30
Completed	30	30

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group Bisclero 6%
Reporting group description: Subject with diameter of ectasic capillary 1-8 mm	
Reporting group title	Group Bisclero 10%
Reporting group description: Subject with diameter of ectasic capillary < 1 mm	
Subject analysis set title	ectasic capillary diameter 1-8mm
Subject analysis set type	Full analysis
Subject analysis set description: Subject treated with low dosage drug product (Bisclero 6%)	
Subject analysis set title	ectasic capillary diameter < 1mm
Subject analysis set type	Full analysis
Subject analysis set description: Subject treated with high dosage drug product (Bisclero 10%)	

Primary: Visual evaluation of efficacy

End point title	Visual evaluation of efficacy[1]

End point description:

The efficacy was determined on the basis of visual assessment of the ectasic vessels and measured on a visual-analogue scale taking into account four criteria: colour, density, relief and vessel surface (VAS scale, 0=maximum severity to 10=absence of lesion).

End point type	Primary

End point timeframe:

15 days after treatment

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Please see enclosed document Evaluation of results

End point values	ectasic capillary diameter 1-8mm	ectasic capillary diameter < 1mm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed				
Units: 60				
VAS = 1	1	1		
VAS = 2	1	12		
VAS = 3	11	6		
VAS = 4	8	5		
VAS = 5	3	1		
VAS = 6	5	3		
VAS = 7	0	1		
VAS = 8	1	1		
VAS = 9	0	0		
VAS = 10	0	0		

Attachments (see zip file)	Statistical evaluation/Valutazione statistica dei risultati.pdf

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 15 days after second treatment	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	8.0
Reporting groups	
Reporting group title	Patient treated with Bisclero 6%
Reporting group description: -	
Reporting group title	Patient treated with Bisclero 10%
Reporting group description: -	

Serious adverse events	Patient treated with Bisclero 6%	Patient treated with Bisclero 10%	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Patient treated with Bisclero 6%	Patient treated with Bisclero 10%	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
Skin and subcutaneous tissue disorders			
hyperpigmentation			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	

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