ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: November 30, 2016

ClinicalTrials.gov ID: NCT02054325

Study Identification

Unique Protocol ID:	CEP 4127.2012
Brief Title:	Study Protocol Comparing Polidocanol Versus Hypertonic Glucose for Treatment of Reticular Veins
Official Title:	A Randomized Triple-blind Study Protocol Comparing Polidocanol Versus Hypertonic Glucose for Sclerotherapy in Treatment of Reticular Veins at the Lower Limbs.
Secondary IDs:	

Study Status

Record Verification:	November 2016
Overall Status:	Completed
Study Start:	September 2012
Primary Completion:	December 2014 [Actual]
Study Completion:	December 2014 [Actual]

Sponsor/Collaborators

Sponsor:	UPECLIN HC FM Botucatu Unesp
Responsible Party:	Principal Investigator Investigator: Dr Matheus Bertanha [mbertanha] Official Title: Professor Affiliation: UPECLIN HC FM Botucatu Unesp
Collaborators:	Fundação de Amparo à Pesquisa do Estado de São Paulo

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: CEP 4127.2012 Board Name: Comitê de Ética em Pesquisa da Faculdade de Medicina de Botucatu Board Affiliation: Conselho Nacional de Saúde (CONEP) Phone: +55 14 3880-1545 Email: tsarden@fmb.unesp.br
Data Monitoring?:	No
Plan to Share IPD?:	Undecided We intend to present data when publish the original article.
Oversight Authorities:	Brazil: National Committee of Ethics in Research

Study Description

Brief Summary:	It will be done a randomized triple-blind study comparing 0,2% polidocanol versus 75% hypertonic glucose of sclerotherapy in lower limbs´ reticular veins. It will be included only adult women with reticular veins on the side of the thighs and mild venous insufficiency (CEAP 1). The primary endpoint will be efficacy, and secondary will be safety.
Detailed Description:	Background. The prevalence of chronic venous disease is high in the general population, mainly in young women, and in milder cases the usual complaint is aesthetic. Various techniques are used for treatment of mild varicose disease, including surgical treatment, laser ablation and sclerotherapy. Reticular veins are those with less than 3mm diameter, bluish and important contribution to the aesthetic damage, and sometimes they are related to local pain and recurrence after treatment of telangiectasias. There is no consensus in the literature about the effectiveness of treatment with sclerotherapy, despite of being an usual procedure with different chemicals. Methods and design. One hundred lower limbs of healthy women between 18 and 69 years will be triple blind randomized to receive treatment with polidocanol 0.2% diluted in 70% hypertonic glucose versus 75% hypertonic glucose for sclerotherapy treatment of reticular veins. The patients will be examined and clinically classified. It will be included patients with reticular veins sited at out's thigh/leg, measuring at least 10cm long, and only one extremity will be included per patient. The patients with varicose disease CEAP 2 or more will not be included. The treatment will be carried out in only one session and the medication volume not exceeding 5 ml. Clinical follow-up protocols will be filled on regular visits on days 0 - 7 - 60 concomitantly with photograph documentation. Supplementary examination for venous mapping with ultrasound pretreatment is performed for all patients. Discussion. This prospective controlled double-blind randomized trial aims to verify and compare the efficacy and safety for sclerotherapy treatment of reticular veins of the lower limbs. The results may help physicians to choose the best sclerotherapy treatment for reticular veins.

Conditions

Conditions:	Varicose Veins
Keywords:	Sclerotherapy varicose veins veins

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	106 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Polidocanol with Glucose An application session 0.2% Polidocanol + 70% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5 ml.	Drug: Polidocanol with Glucose An application session 0.2% Polidocanol + 70% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5 ml. Return to a week to investigate the adverse effects and 2 months for proof of efficacy and adverse effects Other Names: • Dodecylpolyethyleneglycolether • Aethoxysklerol • Varithena
Active Comparator: Glucose An application session 75% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5ml.	Drug: Glucose An application session 75% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5 ml. Return to a week to investigate the adverse effects and 2 months for proof of efficacy and adverse effects

Arms	Assigned Interventions
	Other Names: • Dextrose

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 69 Years

Gender: Female

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- females
- with at least 10 cm from the lateral reticular veins of the leg or thigh of the leg
- clinical classification of chronic venous disease C1(mild venous disease),
- minimum age of 18 year-old and maximum age 69 year-old
- agreement with the study
- signing the free and informed consent (IC)
- not use anticoagulant drugs .

Exclusion Criteria:

- male
- varicose disease in any quantity or location with clinical classification of chronic venous disease different of C1(mild venous disease)
- restrict mobility
- arterial insufficiency
- be allergic to any substance that may be related to the study drugs
- any cause of dermatitis on application site
- free of comorbidities clinically serious as diabetes mellitus, heart failure, respiratory failure, uncontrolled hypertension with medication, and uncontrolled hypothyroidism
- pregnancy
- previous deep vein thrombosis (DVT)
- family history of DVT
- thrombophilia
- do not agree with the search terms

Contacts/Locations

Study Officials: Matheus Bertanha, Professor
Study Principal Investigator
UPECLIN

Locations: Brazil
School of Medicine at Botucatu- Paulista State University- UNESP, São Paulo, Brazil
Botucatu, SP, Brazil, 18607030

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Pre-Assignment Details	Some patients (n=6) were withdrawn because did not appear at the previous scheduled appointments, and were replaced for new ones. In order to avoid loss of individuals we have decided to include 6 more patients.

Reporting Groups

	Description
Polidocanol With Glucose	An application session 0.2% Polidocanol + 70% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5 ml. Polidocanol with Glucose: An application session 0.2% Polidocanol + 70% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5 ml. Return to a week to investigate the adverse effects and 2 months for proof of efficacy and adverse effects
Glucose	An application session 75% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5ml. Glucose: An application session 75% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5 ml. Return to a week to investigate the adverse effects and 2 months for proof of efficacy and adverse effects

Overall Study

	Polidocanol With Glucose	Glucose
Started	51	55
Completed	43	50
Not Completed	8	5
Lost to Follow-up	8	5

Baseline Characteristics

Reporting Groups

	Description
Polidocanol With Glucose	An application session 0.2% Polidocanol + 70% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5 ml. Polidocanol with Glucose: An application session 0.2% Polidocanol + 70% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5 ml. Return to a week to investigate the adverse effects and 2 months for proof of efficacy and adverse effects
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Baseline Measures

		Polidocanol With Glucose	Glucose	Total
Overall Number of Participants		43	50	93
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	43 participants	50 participants	93 participants
	<=18 years	0 0%	0 0%	0 0%
	Between 18 and 65 years	43 100%	50 100%	93 100%
	>=65 years	0 0%	0 0%	0 0%

		Polidocanol With Glucose	Glucose	Total
Gender, Male/ Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	43 participants	50 participants	93 participants
	Female	43 100%	50 100%	93 100%
	Male	0 0%	0 0%	0 0%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Efficacy in Treating Reticular Veins by Photographs: Mean Percent Reticular Vein Disappearance Two Months After Treatment.
Measure Description	Photographs were performed pretreatment and two months after the treatment, these were analyzed for efficacy in treat reticular veins by two blind analyzers objectively with measurement through the use of free software ImageJ.
Time Frame	Mean Percent of reticular vein disappearance two months after treatment
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

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Measured Values

	Polidocanol With Glucose	Glucose
Number of Participants Analyzed	43	50

	Polidocanol With Glucose	Glucose
Efficacy in Treating Reticular Veins by Photographs: Mean Percent Reticular Vein Disappearance Two Months After Treatment. Mean (Standard Deviation) Unit of measure: % of Reticular Veins that Disappeared	95.17 (9.09)	85.40 (17.04)

2. Secondary Outcome Measure:

Measure Title	The Safety of the Treatment: Mean Percent of Skin Hyperpigmentation Two Months After Treatment
Measure Description	Skin hyperpigmentation was defined as a brownish hue stain superimposing the previous treated vein site (by visual photographic analyses). Skin hyperpigmentation was firstly evaluated according to its occurence and labeled as "Yes" or "No". Afterwards, when there was stain in the previous treated area, a line was drawn on the stain with Image J software , and the Mean Percent of Skin Hyperpigmentation was proportionaly compared with length of vein treated, previuos mesuread (mean and SD).
Time Frame	Two months after treatment.
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Polidocanol With Glucose	An application session 0.2% Polidocanol + 70% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5 ml. Polidocanol with Glucose: An application session 0.2% Polidocanol + 70% Glucose to treat reticular veins of the lower limb selected, with a maximum volume of 5 ml. Return to a week to investigate the adverse effects and 2 months for proof of efficacy and adverse effects
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Measured Values

	Polidocanol With Glucose	Glucose
Number of Participants Analyzed	43	50
The Safety of the Treatment: Mean Percent of Skin Hyperpigmentation Two Months After Treatment Mean (Standard Deviation) Unit of measure: Percent of Skin Hyperpigmentation	5.75 (7.02)	9.66 (11.67)

Reported Adverse Events

Time Frame	Right after two months post procedure
Additional Description	Hyperpigmentation: Linear measure above the projection area of hyperpigmentation post procedure. The length of this line was provided by the Image J software (ImageJ is a public domain, Java-based image processing program developed at the National Institutes of Health)

Reporting Groups

	Description
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Serious Adverse Events

	Polidocanol With Glucose	Glucose
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/43 (0%)	0/50 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 1%

	Polidocanol With Glucose	Glucose
	Affected/At Risk (%)	Affected/At Risk (%)
Total	22/43 (51.16%)	31/50 (62%)
Skin and subcutaneous tissue disorders		
Hyperpigmentation A [1] †	22/43 (51.16%)	31/50 (62%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, DeCS http://decs.bvs

[1] Dark pigmentation of skin after injection

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

All Principal Investigators ARE employed by the organization sponsoring the study.

Results Point of Contact:

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