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Reducing Hyperpigmentation After Sclerotherapy

Submission date
03/04/2020

Recruitment status
No longer recruiting

Registration date
20/04/2020

Overall study status
Completed

Last Edited
11/12/2020

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Varicose veins are swollen blood vessels that are most commonly in the lower legs and feet. They may be dark blue or purple, and are often lumpy or twisted in appearance. People can experience swollen, itchy, aching and uncomfortable legs, feet and ankles. One treatment for varicose veins is called sclerotherapy, which involves an injection into the vein which causes the blood in the vein to clot and vein to collapse and shrink. One of the side effects of this treatment is that patients can be left with discolouration of the skin which can appear darker /hyperpigmented.

This study aims to find out if adding a drug called sulodexide to the standard sclerotherapy treatment for patients with varicose veins can reduce the presence of hyperpigmentation following the procedure without affecting the intended therapy of vein elimination or increasing the risk of major bleeding

Who can participate?
Patients who are aged 18 to 65 years with telangiectatic, reticular, or varicose veins in their lower limbs who are suitable candidates for sclerotherapy

What does the study involve?
Half of the participants will receive standard sclerotherapy treatment. The other half will receive sulodexide 7 days before the scheduled sclerotherapy. All participants will be advised to wear compression stockings for 7 days afterwards. At 1 and 3 months participants will return for follow up appointments to check for the success of the sclerotherapy and for hyperpigmentation.

What are the possible benefits and risks of participating?
Possible benefits of this treatment could be improved patient satisfaction, which is very important in a procedure mostly done for cosmetics reasons. Additionally, faster improvement in the emotional wellbeing and quality of life of the patient.

With the reduction of the incidence of post-sclerotherapy hyperpigmentation, the possibility to treat larger veins with sclerotherapy can be contemplated, and possibly avoid a more expensive

procedure like surgical stripping; this can be important in the socioeconomic population where sclerotherapy is the only possible treatment.

Where is the study run from?
CLINEDEM, ISSSTECALI and Hospital General Issste 5 de Diciembre (Mexico)

When is the study starting and how long is it expected to run for?
From January 2018 to September 2019

Who is funding the study?
This study is investigator-initiated and funded

Who is the main contact?
Dr Alejandro Gonzalez Ochoa
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
8936-042019

Study information

Scientific Title
Reducing Hyperpigmentation After Sclerotherapy (RHyAS) study: a multicenter, randomized, clinical trial.

Acronym
RHyAS study

Study objectives
The use of sulodexide in patients with varicose vein treated with sclerotherapy can reduce the incidence of hyperpigmentation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/11/2017, the Universidad Autónoma de Baja California (Coordination de Posgrado e Investigacion. av Alvaro Obregon y Julian Carrillo s/n Colonia Nueva cp 21100
Edificio de Rectoria, Mexicali Baja California, Mexico; +52 686 551 9497; anahernandez@uabcinvestigacion.net)

Primary study design
Interventional

Study design
Prospective, multicentric, randomized controlled trial, using a parallel-group design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hyperpigmentation following sclerotherapy for varicose veins

Interventions
Participants who were included with telangiectasia, reticular or varicose veins who were candidates for sclerotherapy. They received Sclerotherapy using polidocanol 1% as sclerosant agent, 10ml maximum dose per session, total of 2 sessions 6 weeks apart. 20-30mmhg compression stockings were used in both groups for 7 days.

Participants were randomly assigned, in a 1:1 ratio, to either group A or group B.

Group A received an oral dose (250 LSU) of sulodexide bid 7 days prior to scheduled sclerotherapy that continued for 3 months.

Group B received the standard sclerotherapy protocol.

Photographic control was taken, and follow-up was done at 1 and 3 months. With the aid of computer software, the treated area was compared for the variables of incidence of pigmentation, the total area of pigmentation, skin-tone increase in pigmented area, vein disappearance, and incidence of major bleeding.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Suldexide 250 LSU bid oral dose for 3 months Polidocanol 1% 10ml maximum dose per session

Primary outcome(s)
1. Incidence of post sclerotherapy hyperpigmentation measured using computer software at baseline, 1 and 3 months
2. Total area of hyperpigmentation measured using computer software at baseline, 1 and 3 months

Key secondary outcome(s)
1. Presence of major bleeding measured using computer software at baseline, 1 and 3 months
2. Clinical response of vein disappearance measured using computer software at baseline, 1 and 3 months

Completion date
01/09/2019

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years
2. Telangiectatic, reticular, or varicose veins in lower limbs
3. Candidate for sclerotherapy
4. BMI 20 to 40 kg/m2
5. Fitzpatrick skin tone I – V
6. Signed consent to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
720

Key exclusion criteria
1. Acute thrombosis
2. History of deep vein thrombosis
3. Deep vein reflux
4. Saphenous vein reflux
5. Pregnancy
6. Bed confinement

7. Long term use of steroidal or nonsteroidal anti-inflammatory drugs (such as corticoids, methotrexate, etc.)
8. Severe leg edema

Date of first enrolment
01/01/2018

Date of final enrolment
01/08/2019

Locations

Countries of recruitment
Mexico

Study participating centre
CLINEDEM
Clinic of Dental and Medical Specialties (CLINEDEM)
Callejón 5 de Mayo and Calle 7 No. 791
Planta Alta
San Luis Rio Colorado
Mexico
83449

Study participating centre
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Av. Calafia No 1115 - 1G
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Study participating centre
Hospital General Issste 5 de Diciembre
Calzada independencia
Centro Civico
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Sponsor information

Organisation
CLINEDEM

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	11/12/2020	Yes	No
Basic results			18/05/2020	No	No