**Participant flow**

Men or women

Age 18-70y

No GSV reflux

Willing participate

History DVT

Pregnancy

Poor general health

anticoagulation

NSAI´s

Not willing to use compression

Fail visit

Fail medication or compression

Abandon study

Sulodexide oral dose 500 LRU-day

1 month

3 months

|  |  |  |
| --- | --- | --- |
| **Inclusion criteria** | **Exclusion criteria** | **Elimination criteria** |
| Age 18 - 65 years.  Telangiectasia, reticular, or varicose veins in lower limbs.  Candidate for sclerotherapy.  BMI 20 – 40 kg/m2.  Fitzpatrick skin tone I – V.  Sign a consent to participate. | Acute Thrombosis.  History of Deep vein thrombosis.  Deep vein reflux.  Saphenous vein reflux.  Pregnancy.  Bed confinement.  Long term use of steroidal or nonsteroidal anti-inflammatory drugs (corticoids, methotrexate, etc.).  Severe leg edema.  Concomitant severe disease (heart, liver, renal, etc.).  Local skin infection.  Severe skin scaring.  Chronic arterial disease.  Fitzpatrick skin tone VI.  Thrombophilia.  Small area to treat (equivalent to < ¼ of the leg superficial area). | Voluntary study withdraws.  Non-compliant with elastic compression.  Voluntary stop taking sulodexide.  Lost to follow-up.  Pregnancy detection during the study period.  Severe disease detected during the study period. |

*Inclusion, exclusion and elimination criteria*

**Baseline Characteristics**

|  |  |  |  |
| --- | --- | --- | --- |
| Patients Characteristics | Study group  (n=359) | Control group  (n=361) | P value |
| Sex  *Female, No., %*  *Male, No., %*  Age, mean, years  BMI, mean, kg/m2  Fitzpatrick skin tone  I, n, %  II, n, %  III, n, %  IV, n, %  V, n, %  Type of veins treated  Telangiectasia (>1mm), %  Reticular (1-3mm), %  Varicose (>3mm), % | 339 (94.4)  20 (6.6)  41 (SD=12.4)  31.94 (SD=4.5)  10 (2.7)  29 (8)  131 (36.4)  146 (40.6)  42 (11.6)  85  87  64 | 337 (93.3)  24 (6.7)  42 (SD 12.8)  30.96 (SD=4.8)  15 (4.1)  34 (9.4)  124 (34.3)  138 (38.2)  47 (13)  83  85  67 | NS  NS  NS  NS  NS  NS  NS  NS  NS  NS  NS  NS |

Population characteristics. SD: Standard deviation, BMI: Body mass index, NS: Not Significant, n: Number patients. Significance set at p< 0.05 using student t-test

**Outcome Measures**

|  |  |  |  |
| --- | --- | --- | --- |
| Treatment Outcome Results | Study group  N= 320 (1-month)  N= 312 (3-months) | Control group  N= 318 (1-month)  N= 297 (3-month) | P value |
| Presence hyperpigmentation  1 month, No, %  3 months, No, %  Total area affected  1 month, %  3 months, %  Skin-tone increase  1 month, %, SD  3 months, %, SD  Major bleeding  1 month  3 months  Therapeutic vein disappearance  1 month, %  3 months, % | 28 (8.7)  16 (5.1)  10.7 (7.9)  4.7 (6.2)  17 (7.9)  6.9 (8.8)  0  0  46  76 | 47 (14.8)  31 (10.4)  18.2 (9.1)  8.6 (9.5)  25 (9.8)  9.5 (10.6)  0  0  48  73 | 0.01  0.02  <0.01  0.04  0.02  NS  NS  NS  NS  NS |

Treatment outcome results. SD: standard deviation. Significance set at P< 0.05 using Chi square test and Student t-test. Relative risk reduction: 41%. Absolute risk reduction: 6.1%.

**Adverse Events**

|  |  |  |  |
| --- | --- | --- | --- |
| **Adverse event** | **Study group** | **Control group** |  |
| Headache, n  Gastrointestinal, n  Major bleeding, n  Need to suspend medication  Need use other  Medication for leg pain  At 1 month, n  At 3 months, n  Need thrombectomy | 5  8  0  0  7  0  9 | 7  6  0  0  28  0  11 |  |
| **Excluded participant**  At 1 month, n  At 3 month, n  total  Lost to follow-up, n  NC compression, n  NC medication, n | 39  8  47  22  17  9 | 43  21  64  29  22  13 |  |

*NC Non- Compliant*