Effects of a Dietary Supplement Composed of Diosmin, Hesperidin, Bromelain, and Ruscus Aculeatus on the Quality of Life in Subjects With Lower Limb Disorders Possibly Prodromal to Chronic Venous Disease

NCT07185386

Status	RECRUITING
Phase	Not Applicable
Sponsor	Ekalab S.r.l.
Enrollment	84 participants

Key Eligibility Criteria

Inclusion (5)

- Both sexes;
- Age e18 years;
- Signed informed consent form for participation in the study;
- Presence of at least one clinical symptom possibly related to chronic venous disease (such as heaviness and/or swelling and/or pain in the lower limbs, nighttime cramps, tired/heavy legs, itching, burning and/or warmth, tingling, or restlessness in the lower limbs);
- Willingness to participate in the study and to comply with the study procedures, as confirmed by signing the written informed consent.

Exclusion (2)

- Pregnancy or current breastfeeding; Women of childbearing potential who are not using adequate birth control methods (either hormonal contraception in the form of contraceptive pills, or barrier birth control methods used in combination with a spermicidal product such as foam, gel, or film).
- \[For the entire duration of the study, women of childbearing potential-defined as those who are less than one year post-menopause or who have not undergone hysterectomy or tubal ligation-must use an effective method of contraception, in accordance with Note 3 of the ICH M3 Guideline. A contraceptive method is considered highly effective if it results in a failure rate of less than 1% per year. Effective contraceptive methods include: hormonal contraceptives containing estrogens and progestins (oral, intravaginal, transdermal) that inhibit ovulation; hormonal contraceptives containing progestins only (oral, injectable, implantable); intrauterine devices (IUDs); hormone-releasing intrauterine systems (IUS); partner vasectomy; sexual abstinence\]; Individuals with chronic venous insufficiency classified as CEAP stages C3-C6 (see Annex 1); Individuals with a positive pitting edema sign detected at Visit 1 after signing the informed consent; Patients with documented deep vein thrombosis within the last 6 months; Current or recent (within the last 4 weeks) use of venoactive and/or anti-edematous products; Individuals scheduled for surgical procedures within 3 months of enrollment; Subjects with a history of heart failure (NYHA Class III-IV), chronic kidney disease, and/or severe hepatic insufficiency; Ongoing oncological or immunosuppressive diseases; Celiac disease; Drug and/or alcohol abuse; Neurological or psychiatric disorders that may impair the validity of informed consent and/or compromise adherence to the study procedures; Known allergy, hypersensitivity, or intolerance to any component of the investigational dietary supplement; Any medical or non-medical condition that, in the opinion of the Investigator, could interfere with the study or make participation unsafe; Subjects currently enrolled in other clinical trials, or who have received another investigational product within 30 days prior to study start; Individuals who have not signed the informed consent form.

Locations (6 total)

AOU Policlinico Sant'Orsola Malpighi, Bologna, BO, Italy
Università degli Studi Magna Graecia, Catanzaro, CZ, Italy
IRCCS San Raffaele Pisana, Roma, Roma, Italy
... and 3 more locations