Lutein by Scleral Iontophoresis in AMD

NCT06925893

Status	RECRUITING
Sponsor	Federico II University
Enrollment	80 participants

Key Eligibility Criteria

Inclusion (3)

- Subjects (male or female) aged e 55 years; Subject able to provide Informed Consent, in compliance with good clinical practice and current legislation
- Subject with age-related macular degeneration (AMD) category 3 in one or both eyes classified according to the criteria reported by "Age-Related Eye Disease Study (AREDS)" based on clinical manifestations:
- Subject in good general health; Manifest spherical equivalent refraction between +4.0 diopters (D) and - 4.0 D; Best corrected visual acuity (BCVA) for glasses d 0.1 LogMAR; Intraocular pressure (IOP) d 20 mmHg; Subjects able to cooperate with the Investigator; Subjects able to meet the requirements of the entire clinical investigation; Subject who qualifies for treatment with Iontoretina according to the approved indication;

Exclusion (4)

- Ocular surgery or other type of invasive intervention within the previous 3 months (of any type, including laser surgery and intravitreal injections) performed on the study eye; Lesions, scars, or abrasions of the ocular components present in the eye under study; Dense opacities of the ocular components of the study eye; Implantation of intraocular lenses (IOLs) in the study eye; Congenital malformations in the study eye; Medical history of ocular hypertension and glaucoma, macular pucker, optic neuropathy, diabetic retinopathy, dry eye syndrome, etc. (limited to the study eye);
- Lutein or zeaxanthin supplementation or any supplementation or with the intention of impacting eye health within the last 4 weeks prior to the screening visit; Known or potential allergy or hypersensitivity and/or history of allergic reactions to any of the components of the medical device or other chemically closely related substances; Subject suffering from type I diabetes, or with a previous case of stroke; Subject suffering from uncontrolled hypertension and heart disease that, in the opinion of the Investigator, does not allow participation in the study or could compromise the results; Subject smoker (more than 20 cigarettes per day); Significant alcohol consumption: more than 2 drinks per day;
- Women of childbearing potential will be excluded from participation in the study if they meet any of the following conditions:
- pregnant; intend to become pregnant during the study treatment period; Concomitant hormone replacement therapy for menopause. Participation in another clinical study within the previous 90 days; Subject unable to follow clinical investigation procedures and follow-up visits;

Locations (1 total)

Federico II University, Naples, Italy