

Study to Assess the Safety and Effectiveness of Beltaven® in Patients With Allergy to Apis Mellifera, Polistes Dominula or Vespula Spp.

NCT07309822

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| Status | RECRUITING |
| Sponsor | Probelte Pharma S.L.U. |
| Enrollment | 27 participants |

Key Eligibility Criteria

Inclusion (7)

- Age 14 years or older at the time of study inclusion.
- Written informed consent, duly signed and dated by the patient or by the legal representative in the case of minors.
- Assent form duly signed and dated by the minor, when applicable.
- Patients with allergy to Apis mellifera, Vespula spp., or Polistes dominula who have experienced a systemic reaction following a hymenoptera sting, either with involvement of multiple organs or exclusively cutaneous.
- Positive intradermal test (mean wheal diameter \geq 5 mm) with Beltaven® diagnostic (allergenic extract of Apis mellifera, Vespula spp., or Polistes dominula).

... and 2 more (see full listing online)

Exclusion (7)

- Patients with severe cardiovascular diseases, active malignant neoplasms or malignancies in remission within the last 5 years, non-stabilized systemic or organ-specific autoimmune diseases, severe mental disorders, or other relevant chronic diseases that may interfere with the study results.
- Patients with known allergy to any of the vaccine excipients.
- Pregnant patients, patients planning to become pregnant during the study period, or breastfeeding patients.
- Patients who have received hymenoptera immunotherapy within the 5 years prior to inclusion or during the study.
- Patients who are to receive immunotherapy with another specific allergen different from the investigational treatment during the study period.

... and 2 more (see full listing online)

Locations (13 total)

Hospital Universitario Vall d' Hebron, Barcelona, Barcelona, Spain
Hospital Universitario de Bellvitge, Barcelona, Spain
Xarxa Assistencial I Universitària de Manresa, Barcelona, Spain
... and 10 more locations