ACE induced Angioedema Study PI Seneff

Eligible patients will be randomized at a 1:1 ratio to receive a single SC injection of either 30 mg icatibant or placebo. Angioedema-associated upper airway symptom assessments will be performed for all patients at baseline and at 0.5, 1, 2, 3, 4, 5, 6, 7 and 8 hours post treatment.

Inclusion Criteria:

1. Male or female, 18 years of age or older.
2. Patient is currently being treated with an ACE inhibitor.
3. Patient presenting with an ACE inhibitor-induced angioedema attack of the head and/or neck region within 12 hours of onset (must be sufficiently less than 12 hours to allow study drug to be given with 12 hours of onset).
4. Angioedema must be considered at least moderate in severity for at least one of the four primary efficacy angioedema-associated upper airway symptoms (difficulty breathing, difficulty swallowing, voice changes, tongue swelling).
5. Patient must have voluntarily signed an Institutional Review Board/Independent Ethics Committee-approved informed consent form after all relevant aspects of the study have been explained and discussed with the patient.
6. Females must have a negative urine pregnancy test prior to administration of the study medication, with the exception of those females who have had a total hysterectomy or bilateral oophorectomy, or who are 2 years post-menopausal.

Exclusion Criteria:

1. Patient has a diagnosis of angioedema of other etiology (eg, hereditary or acquired angioedema, allergic angioedema [eg, food, insect bite or sting, evident clinical response to antihistamines and/or corticosteroids], anaphylaxis, trauma, abscess or infection or associated disease, local inflammation, local tumor, post-operative or post-radiogenic edema, salivary gland disorders, other [non-ACE inhibitor] druginduced angioedema).

2. Patients with a family history of recurrent angioedema.

3. Patients who have had a previous episode(s) of angioedema while not on ACE inhibitor therapy.

4. Patients with acute urticaria (itchy, erythematous wheals).

5. Patients who have an intervention to support the airway (eg, intubation, tracheotomy, cricothyrotomy) due to the current attack of angioedema.

6. Patient has any of the following vascular conditions that, in the judgment of the investigator, would be a contraindication to participation in the study.

* Unstable angina pectoris or acute myocardial ischemia.

*Hypertensive urgency or emergency (diastolic blood pressure [DBP] >120 mm Hg or systolic blood pressure [SBP] >180 mm Hg).

* Within 1 month of a stroke or transient ischemic attack.

* New York Heart Association (NYHA) heart failure Class IV.

7. Patient has a serious or acute condition or illness that, in the judgment of the investigator, would interfere with evaluating the safety and/or efficacy assessments of the study.

8. Patient is pregnant or breast feeding.

9. Patient has participated in another investigational study in the past 30 days.

10. Patient is unable to understand the nature, scope, and possible consequences of the protocol, or is unlikely or unable to comply with the protocol assessments, or is unlikely to complete the study for any reason.

11. Patients who are not suitable for the study in the opinion of the investigator.

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