



MEETING ABSTRACT

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# Analysis of icatibant for the treatment of laryngeal hereditary angioedema attacks in the FAST-3 study

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## Background

The efficacy and safety of icatibant for the treatment of edematous hereditary angioedema (HAE) attacks was established in three Phase III trials, including the For Angioedema Subcutaneous Treatment-3 study (FAST-3; NCT00912093). Here, data from the double-blind, controlled phase and open-label extension (OLE) of FAST-3 were analyzed post-hoc to specifically evaluate icatibant for the treatment of laryngeal attacks, which can cause potentially fatal airway obstruction.

## Methods

Controlled phase: adults with HAE type I/II were randomized to a single subcutaneous injection of icatibant 30 mg or placebo for their first mild-to-moderate laryngeal attack or moderate-to-very severe cutaneous/abdominal attack; severe laryngeal attacks were treated with open-label icatibant. OLE: attacks were treated with up to three icatibant injections, at  $\geq 6$ -hour intervals. Three outcomes were analyzed for first icatibant-treated laryngeal attacks: 1) time to onset of symptom relief (earliest of three consecutive measurements for which there was a 50% reduction of patient-assessed 5-symptom composite 100 mm visual analog scale [VAS]); 2) time to almost complete symptom relief (earliest of three consecutive measurements for which all VAS symptom scores  $< 10$  mm); 3) patient- and investigator-assessed time to initial symptom improvement. Reinjection rates were also recorded.

## Results

For first icatibant-treated laryngeal attacks in the controlled phase or OLE ( $n=27$ ), median (95% CI) time to onset of symptom relief was 2.0 (1.5-3.5) hours, median (95% CI) time to almost complete symptom relief was 6.0 (3.0-24.3) hours, and median (95% CI) patient- and

investigator-assessed time to initial symptom improvement was 0.7 (0.4-0.9) and 0.8 (0.5-1.1) hours, respectively. In the OLE, 41/43 (95.3%) laryngeal attacks were treated with one icatibant injection, 2/43 (4.7%) were treated with two injections, and none required three injections.

## Conclusions

Icatibant provided symptom relief for mild-to-severe laryngeal HAE attacks in FAST-3. In the OLE, almost all laryngeal attacks were treated with one injection only.

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