Pharmacokinetic, pharmacodynamic and safety comparative phase 1/2 study between FMXIN002, a fast acting, dry powder epinephrine intra-nasal formulation, and IM autoinjector under simulated allergic reaction conditions.

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The need

- Epinephrine autoinjectors are the standard of care for severe allergic reactions, however, they are frequently underused or misused[1], leading to morbidity and mortality[2].
- Correct use of epinephrine auto injectors is low: just 16% - 32%[3].

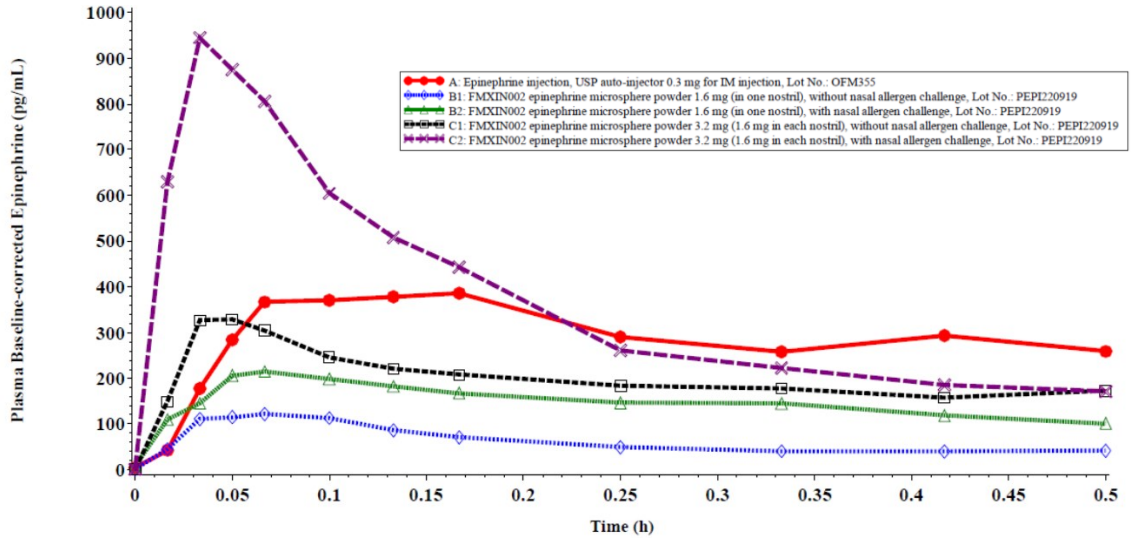
FMXIN002, a nasal powder spray of epinephrine was developed for the emergency treatment of allergic reactions (Type I) including anaphylaxis.

We compared the pharmacokinetics, pharmacodynamics and safety of intranasal FMXIN002 to IM autoinjector.

Clinical study design

An open-label trial in 12 adults with seasonal allergic rhinitis. PK/PD and safety were compared between IN administered FMXIN002 (1.6 mg, 3.2 mg) with and without a nasal allergenic challenge and IM epinephrine 0.3mg, autoinjector.

Results: Epinephrine in plasma in first 0.5 hour



PK Summary	Nasus (3.2mg) normal conditions	Nasus (3.2mg) + allergic challenge	EpiPen
AUC (0-t) (mean, hr*pg/ml)	668	672	470
Cmax (mean, pg/ml)	447	1,100	550
Tmax (median, min.)	6.0	2.5	9.0
T100pg/ml (median, min.)	3.0	1.0	3.0

- PD response of the nasal spray was similar to EpiPen.
- The nasal spray was well tolerated, no SAE.
- The nasal spray is stable at room temperature for 2 years.

Conclusion:

Nasus' epinephrine nasal powder spray offers faster absorption of epinephrine and needleless user-friendly delivery.

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References:
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2.Chooniedass, Rishma, et al. *Annals of Allergy, Asthma & Immunology* 119.2 (2017): 108-110.
3. Bonds RS et al. Ann Allergy Asthma Immunol . 2015;114(1):74e76.e2;