In vitro and in vivo study of inhaled tacrolimus colloidal dispersion in healthy human volunteers


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Introduction

Tacrolimus (TAC) is a cyclic polypeptide derived from Streptomyces tsukubaensis. It is a potent immunosuppressant used in the treatment of organ transplantation.

Objectives

The aim of the present study was to evaluate the pharmacokinetics and safety of an inhaled tacrolimus formulation (inhaled TAC).

Methods: Formulation characterization

- Aerodynamic characterization using an SMAC apparatus
- Physicochemical characterization
- In-vitro dissolution studies

Methods: In vivo tolerability study

- Animal study: Beagle dogs
- Evaluation of systemic exposure: Serum TAC levels

Results and Discussions

- In vitro: Significant reduction in particle size
- In vivo: Tolerability and efficacy evaluated

Conclusions

- Formulation: A promising inhaled tacrolimus dispersion
- Safety: Further studies needed

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References