

Administration of Transferon Oral® ameliorates allergic rhinitis in an ovalbumin-induced mouse model.

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INTRODUCTION

Allergic Rhinitis (AR) is a type-I hypersensitivity mediated by IgE and characterized by itching, sneezing, runny nose, nasal congestion, hypertrophy of the turbinates, fatigue, and irritability(1). Transferon-Oral® is a complex mixture of smaller than 10 kDa peptides derived from leucocyte lysates(2). The Mass spectrometry analysis shows that Transferon Oral® is mainly composed of 22 human proteins, Extracellular monomeric Ubiquitin (EmUb) and Ankyrin (Ank) among them(3). EmUb and Ank might mediate allergic processes through modulation of the CXCR4/CXCL12 axis (cell migration and cytokine modulation) and preventing binding of IgE to FcεR1, respectively(4).

OBJECTIVE

Evaluate the immunomodulatory effects of Transferon-Oral® in an OVA-induced AR murine model (IgE anti-OVA, cell infiltrate in NALT, and clinimetric analysis).

METHODS

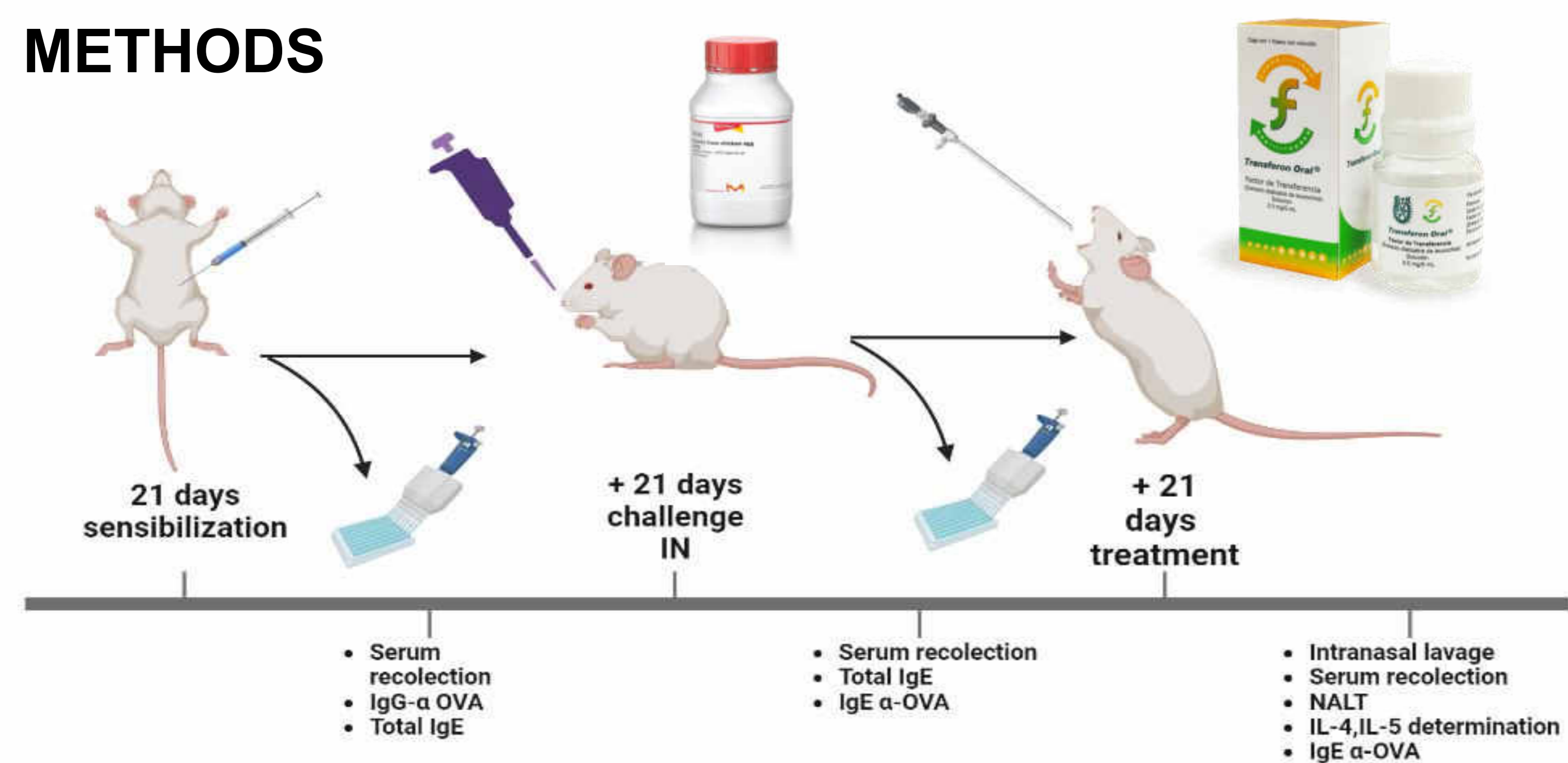


Figure 1. General scheme for the establishment and treatment of allergic rhinitis with Transferon-Oral®.

RESULTS AND DISCUSSION

1. CLINIMETRY

The administration of Transferon-Oral® reduces the clinical signs of scratching, peeling, redness, tearing, and rhinoconjunctivitis in RA.



Figure 2. Establishment of allergic rhinitis 21 days of the challenge. **A)** Control mouse without allergic rhinitis. **B)** Positive control mouse, established allergic rhinitis, showing signs of rhinoconjunctivitis, tearing, and inflammation in the nasal area. **C)** Mouse with established allergic rhinitis + challenge and treated with Oral Transferon shows improvement in rhino conjunctivitis, tearing, and reduction of nasal inflammation.

ETHICAL APPROVAL

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2. SERUM LEVELS OF SPECIFIC IgE

The administration of Transferon-Oral® significantly decreased Anti-OVA IgE levels ($F=10.13$ df (2,62) $P < 0.002$).

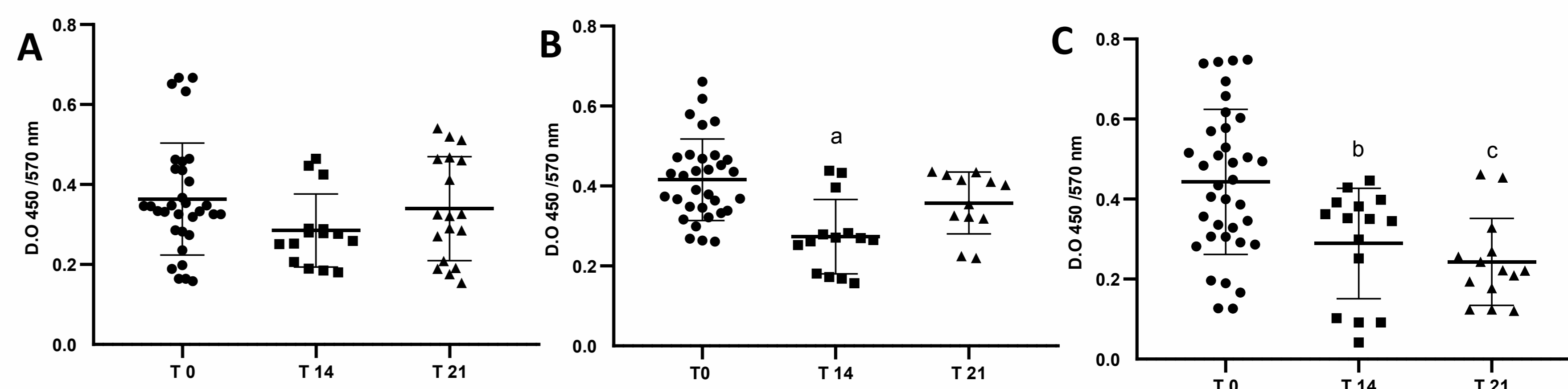


Figure 3. Determining specific IgE in a murine model of allergic rhinitis over 21 days. **A)** Allergic rhinitis + challenge optical density of the positive control for rhinitis with challenge; **B)** Allergic rhinitis without challenge levels of the self-recovery group, rhinitis without challenge with OVA, ($F=10.93$ df (2,55) $P < 0.001$); using the Tukey post-hoc test, it is found that $a = P < 0.05$ **C)** Allergic rhinitis + challenge + Transferon-Oral® [0.750µg] administration of Oral Transferon in mice with allergic rhinitis and challenge results in a significant decrease in their levels of specific IgE ($F=10.13$ df (2,62) $P < 0.002$); using the Tukey post-hoc test, it is found that $b = P < 0.05$ when comparing T0 vs T14 and $c = P < 0.001$ when comparing T0 vs T21.

3. HISTOPATHOLOGY

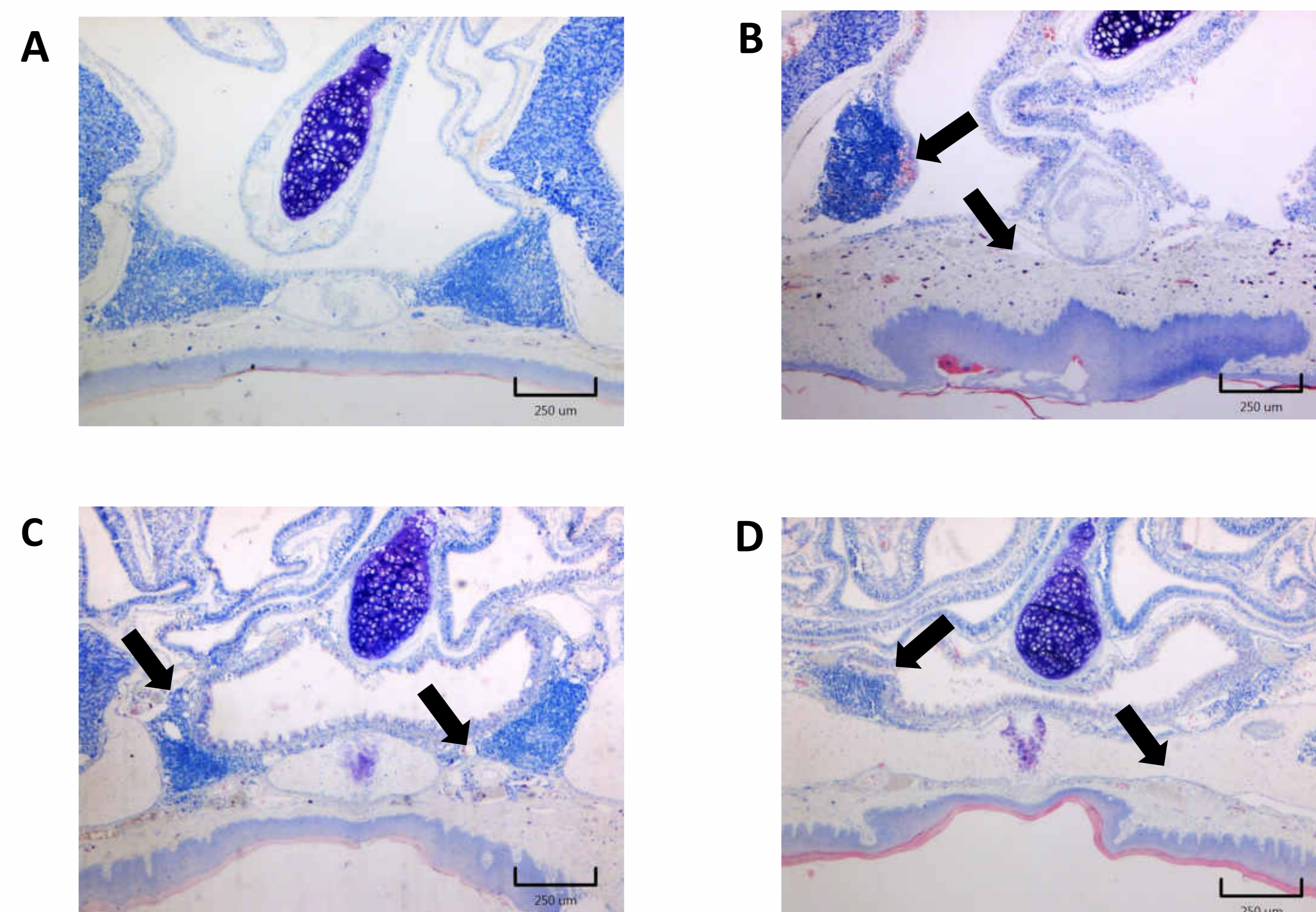


Figure 4. Histopathological staining of NALT. **A)** Control (healthy mice), **B)** Positive control (allergic rhinitis + Challenge), **C)** Self-recovery group without Challenge, **D)** Allergic rhinitis + Challenge + Transferon-Oral® group (0.750 µg/200µL).

CONCLUSION

Transferon Oral® is a product that has been perfected over time. Nowadays, the requirements demanded by regulatory entities are more strict. Even though there is clinical evidence supporting the effectiveness of this immunomodulator, it is compulsory to develop a non-clinical model that supports the use of Transferon Oral® as an immunomodulator in AR. The data from this study shows that Transferon Oral® decreases clinical signs, cellular infiltration in NALT, and anti-OVA IgE levels in a murine model of AR. Taking all into account, these positive results support Phase 2 clinical trials of Transferon Oral® in patients with RA.

FUNDING

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