

# High dose pollen intralymphatic immunotherapy: two RDBPC trials question the benefit of dose increase

Lars Olaf Cardell<sup>1</sup>, Laila Hellkvist<sup>1</sup>, Eric Hjalmarsson<sup>1</sup>, Dan Weinfeld<sup>2</sup>, Alsog Dahl<sup>3</sup>, Agneta Karlsson<sup>1</sup>, Marit Westman<sup>4</sup>, Karin Lundkvist<sup>1</sup>, Ola Winquist<sup>5</sup>, Susanna Kumlien Georén<sup>1</sup>, and Ulla Westin<sup>6</sup>

<sup>1</sup>Karolinska Institutet Institutionen for klinisk vetenskap intervention och teknik

<sup>2</sup>Sodra Alvsborgs sjukhus Boras

<sup>3</sup>Goteborgs universitet Institutionen for Biologi och Miljovetenskap

<sup>4</sup>Karolinska Institutet Institutionen for medicin Solna

<sup>5</sup>ABC labs Biomedicum Stockholm Sweden

<sup>6</sup>Skanes universitetssjukhus Lund

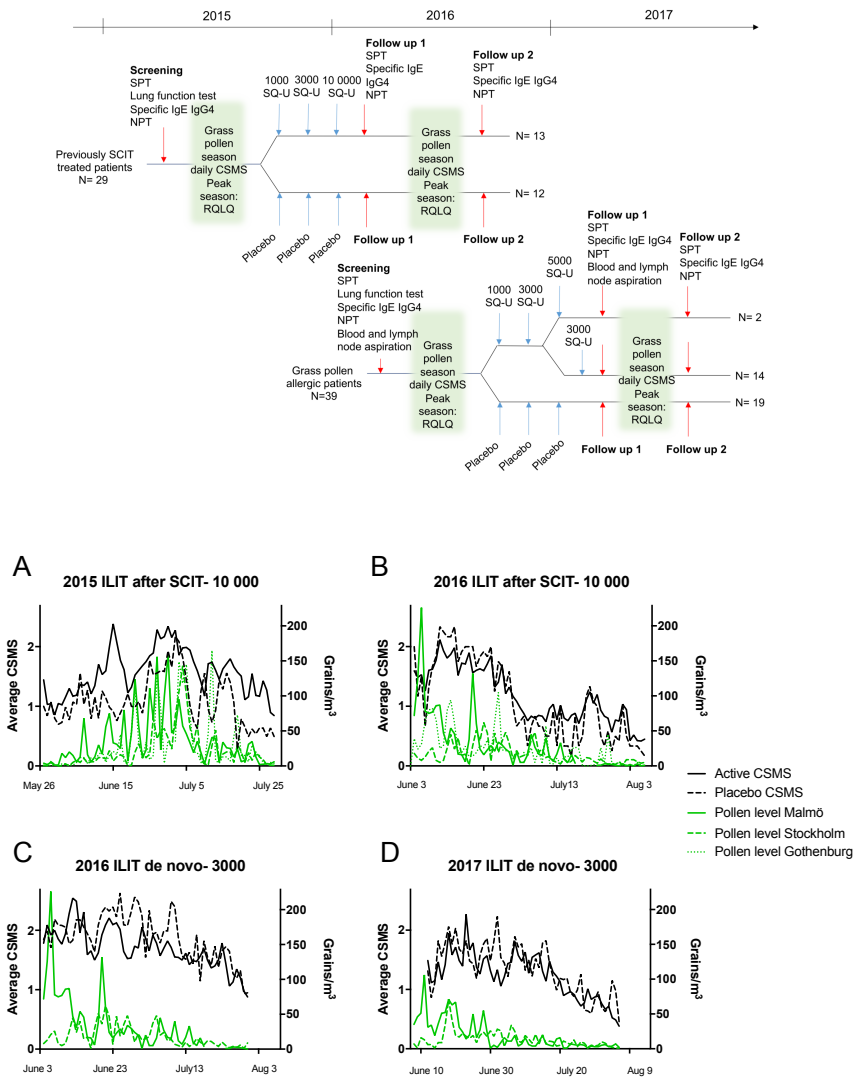
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## Abstract

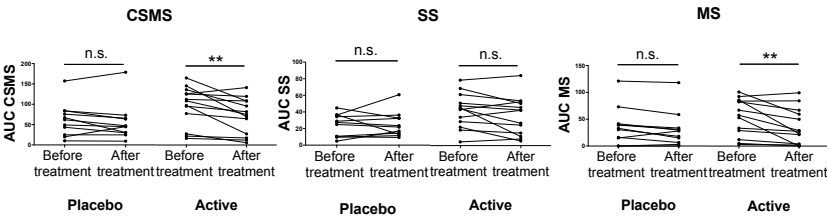
**Background** The same dosing schedule, 1000 SQ-U times three, with one-month intervals, have been evaluated in most trials of intralymphatic immunotherapy (ILIT) for the treatment of allergic rhinitis (AR). The present studies evaluated if a dose escalation in ILIT can enhance the clinical and immunological effects, without compromising safety. **Methods** Two randomized double-blind placebo-controlled trials of ILIT for grass pollen induced AR were performed. The first included 29 patients that had recently ended 3 years of SCIT and the second contained 39 not previously vaccinated patients. An up-dosage of 1000-3000-10 000 (5000 + 5000 with 30 minutes apart) SQ-U with one month in between was evaluated. **Results** Doses up to 10 000 SQ-U was safe after recent SCIT. The combined symptom-medication scores (CSMS) were reduced by 31% and the grass specific IgG4 levels in blood were doubled. In ILIT de novo, the two first patients that received active treatment developed serious adverse reactions at 5000 SQ-U. A modified up-dosing schedule; 1000-3000-3000 SQ-U appeared to be safe but failed to improve the CSMS. Flow cytometry analyses showed increased activation of lymph node derived dendritic but not T-cells. Quality of life and nasal provocation response did not improve in any study. **Conclusion** ILIT in high doses after SCIT appears to further reduce grass pollen induced seasonal symptoms and may be considered as an add-on treatment for patients that do not reach full symptom control after SCIT. Up-dosing schedules de novo with three monthly injections that exceeds 3 000 SQ-U should be avoided.

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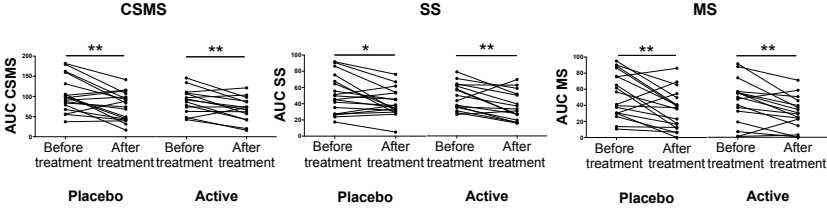
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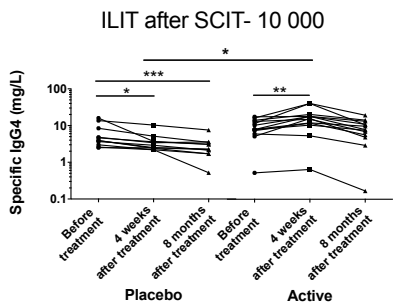
A. ILIT after SCIT- 10 000



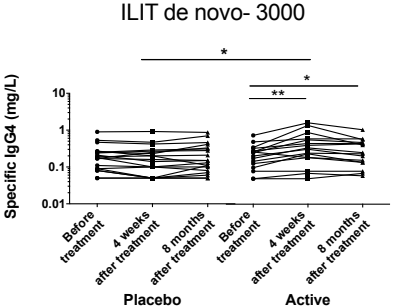
B. ILIT de novo- 3000



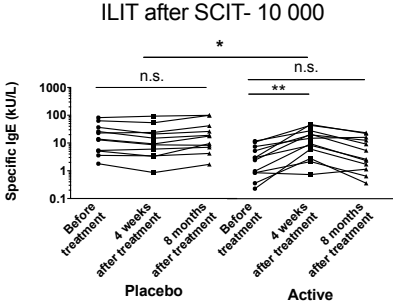
A



B



C



D

