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Extended Abstract
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More than 22 years of clinical studies on anti-pseudomonas IgY to cystic fibrosis patients

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Objectives: Clinical studies have been running in Sweden and in Europe for 22 years with CF-patients on Anti-pseudomonas IgY (Anti-PA IgY) to prevent infections with Pseudomonas aeruginosa (PA) to find out efficacy and adverse events. The promising results gave Anti-PA IgY an Orphan Drug Designation in 2016. Studies: Phase II study was conducted during 1995 -2002: Two groups with intermittently PA-infected patients: one group got Anti-PA IgY, the other group was without IgY. Microbiologists did not know from which group the analyses came from. A prolonged study in Sweden continued 2002-2011. Pregnancy: Two CF women, whereof one twice, were on Anti-PA IgY during pregnancies. Transplanted: One boy transplanted 12 years ago due to infections w. PA and Atyp.Mycobact. Phase III study 2002 -2017: A multicenter study from nine European countries.

Results: Phase II: Group with Anti-PA IgY: 2.35 positive PA cultures/100 months; Untreated group: 7 positive PA/100 months. The duration from first to second colonization with PA was significantly prolonged for the treated versus the control group (Kaplan-Meier p=0.015). The time from first PA infection until chronic infection occurred was prolonged in the Anti-PA IgY treated group. The time until PA was transformed to the severe mucoid form was prolonged. Lung function and BMI were well preserved. Prolonged group: similar effects as those in the first study. Three pregnancies have been carried out well and gave birth to three healthy babies. Transplanted pat.: No new pseudomonas or atypical mycobacterium after transplantation. The few infections in the treated group minimized the need for antibiotics. Phase III: The study was finished in June 2017. Totally 144 countable patients had been included. The results will be ready in spring 2018. All patients have gargled more than 250.000 times and no adverse events have been reported.

Discussion: Anti-PA IgY has shown good results both in efficiency and absence of adverse events. It reduces the use of antibiotics and thus also the risk of resistant bacteria. Gargling is convenient to use. Treatment is cost effective. Cost for Anti-PA IgY is much less than the costs for antibiotics. The costs for days of illness and for hospitalization will be much lower.

Conclusion: Hopefully the now running double-blind, randomized phase III study will give results as expected and Anti-PA IgY might be registered and physicians will be able to give anti-PA IgY to all eligible CF patients.

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