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Sponsor/company:	sanofi-aventis	clinicaltrials.gov Identifier:	NCT00599417
		Study Code:	BACLY_L_03329
Generic drug name:	Bacterial Lysates	Date:	18/Sep/2009

Title of the study:	Prospective, pivotal unicentre, randomized double-blind, placebo-controlled study, to evaluate efficacy and safety of Bacterial Lysates (Pulmonarom®) in the prevention of respiratory tract infections / BACLY_L_03329		
Investigator(s):	Dr. Francisco Espinosa Rosales Insurgentes Sur 3700-C. Col. Insurgentes Cuicuilco C.P. 04530 Mexico D.F. Phone: (+52) 55 1084 0900 ext. 1485 Fax: (+52) 55 1084 0900 ext. 1337 Email: espinosa_francisco@yahoo.com.mx		
Study center(s):	Mexico (1 site)		
Publications (reference):	No publications have been done up to date		
Study period: Date first patient enrolled: 12-dec-2007 Date last patient completed: 12-sep-2008		Phase of development: Phase IV	
Objectives:	Primary: To evaluate the efficacy of Pulmonarom in the decrease of interleukin-4/interferon γ index after second period of treatment. Secondary: - To evaluate the efficacy of Pulmonarom in the prevention of upper respiratory tract infections symptoms through patient evaluation of fever or respiratory presence after second period of treatment. - To evaluate loss of working or study days after second period of treatment. - To evaluate the safety and tolerability of Pulmonarom in the population under study.		
Methodology:	This study is a prospective, pivotal, unicentre, randomized, double-blind, placebo-controlled, comparative with Bacterial Lysates (Pulmonarom ®)		
Number of patients:	Planned: 80	Randomized: 80	Treated: 80
Evaluated:	Efficacy: 52	Safety: 80	
Diagnosis and criteria for inclusion:	Male and female patients of 6 months to 6 years of age with history of relapse or recurrence of respiratory infections or disease, with chronic respiratory disease as asthma, bronchitis or sinusitis and that haven't taken immunology response stimulants during the previous 30 days.		
Investigational product: Dose: Administration:	Bacterial Lysates 3 mL daily for 10 days, followed by 30 days free of medication and then 10 days of administration of the drug Oral		
Duration of treatment: 20 days		Duration of observation: 70 days	

Reference therapy: Dose: Administration:	Placebo controlled 3 mL daily for 10 days, followed by 30 days free of medication and then 10 days of administration of the drug Oral
Criteria for evaluation:	
Efficacy:	Decrease of interleukin-4/interferon gamma index.
Safety:	Adverse events and laboratory evaluations
Statistical methods:	Efficacy variables: Primary efficacy variables The primary variable according to the objective in the interleukin-4/interferon gamma index, evaluating the index decrease, this is measure at visit 1 and in visit 4 and 6, for what beside establishing the confidence interval about the value of the decrease, also it will be possible realize the multivariate analysis of the profile of the decrease obtained throughout the time of study. No transformation appears for the mentioned index. Secondary efficacy variables The secondary efficacy variables were referred to the changes in the individual values for the increase of the value of interferon and in the interleukin-4 changes values alter the second treatment period. They will register on the basis of the clinical history and the results obtained in the evaluations realized to the patients in the different visits, the patients' frequency that perceive prevention in the infections of the respiratory top tract, or in the absence of symptoms as fever or symptoms of respiratory diseases, after the second period of treatment. There will be evaluated the loss of days of work or study by the presence of respiratory diseases after the second period of treatment. Safety variables: Adverse events All the adverse events reported will be register along the study.

Summary:	For the efficacy variable, there were not enough values for the interleukin 4, for this reason the interleukin-4/interferon gamma index can not be calculated, an individual analysis between interleukin 10, interferon gamma and TGF-beta (Transforming growth factor). For the interleukina-10 a statistical significant difference was presented between Pulmonarom and Placebo (p=0.034). For the interferon gamma there were not a statistical significant difference between Pulmonarom and Placebo (p=0.250). For the TGF-beta there were not a statistical significant difference between Pulmonarom and Placebo (p=0.448). All the demographic variables are homogeneous to the revenue of the patients in the study, by what it is fulfilled by the homogeneity of the information. For the loss of days of work or study because of respiratory disease there was not statistical significant difference between both groups of treatments (p=0.185). Adverse events were presented in 20% of the patients in each group without statistic significant differences (p=0.775).
Efficacy results:	For the interleukina-10 a statistical significant difference was presented between Pulmonarom and Placebo (p=0.034), because it was kept constant for Pulmonarom (24 pg/mL in visit 1 y 22 pg/mL in visit 6) and statically decreasing (p=0.001) for the placebo group (22 pg/mL to 10 pg/mL). For the interferon gamma there were not a statistical significant difference between Pulmonarom and Placebo (p=0.250) that change of 18 pg/mL to 15 pg/mL for the Pulmonarom group this is not a significant change due to the number of patients, but the values of the placebo group kept constant of 12 pg/mL to 13 pg/mL For the TGF-beta there were no statistical significant differences between Pulmonarom and Placebo (p=0.448), the value change of 32893 units to 37363 units in the Pulmonarom group this is not a significant change but for the placebo group kept constant, because in the visit 1 the mean value was 31277 and in the visit 6 change to 36309. Though there are no significant differences due to the absenteeism between both treatments for respiratory disease (p=0.185) is observed that this owes the number of patients to itself since 4 patients of placebo appear for only 1 patient who received Pulmonarom.
Safety results:	Adverse events were presented in 20% of the patients in each group without statistic significant differences (p=0.775) The adverse events were 19 and are the following: Pharyngitis: 5 cases Chickenpox: 1 case Flue: 2 cases Rhynopharyngitis: 5 cases Fever: 1 case Exanthema: 2 cases Conjunctivitis: 1 case Rhinorrhea: 2 cases
Date of report:	06-Aug-2009