

Title	1. <i>Early antibiotic treatment in Pseudomonas aeruginosa eradication in cystic fibrosis patients: a randomised policentric study on two different protocols</i>
Project Coordinator	Giovanni Taccetti, MD (g.taccetti@meyer.it)
Internal Collaborators	Vanessa Boni, MD Cesare Braggion, MD - Silvia Campana, Microbiologist Francesca Trevisan, MD Anna Silvia Neri, MD – Lucia Zavataro, Secretary
Study design	Randomized, parallel group, multicentre study (Partners: CF Centre of Ancona, Brescia, Cagliari, Catania, Cerignola, Cesena, Gualdo Tadino, Livorno, Matera, Messina, Milano, Napoli, Palermo, Parma, Potenza, Roma - Bambin Gesù, Soverato, Teramo, Torino Adult, Torino Paediatric, Treviso, Gaslini Hospital) aimed to compare the effectiveness of two antibiotic treatment.
Grant by	Italian Cystic Fibrosis Research Foundation (#17/2007, 2 years, E. 53.000) and Kiwanis Club Firenze (1 year, E. 9.600)
Background and aims	The chronic colonisation of <i>P. aeruginosa</i> (<i>Pa</i>) is an unfavourable event in patients with cystic fibrosis (CF), as it is associated with progressive deterioration of pulmonary function. Elimination of germs from the respiratory tract is possible only with early antibiotic treatment immediately upon first isolations. Since penetration of antibiotics in CF patient secretions is difficult, a combination of inhaled antibiotics and per os appears particularly attractive. Preliminary experience suggests that early antibiotic treatment is effective in eliminating <i>Pa</i> from the airways. To date, no large-scale controlled randomised studies have been performed as a point of reference to verify treatment efficacy levels. The main aim of this large-scale multicentre randomised trial is to compare the efficacy of (A) ciprofloxacin per os + inhaled colistin versus (B) ciprofloxacin per os + inhaled tobramycin in the eradication of first <i>Pa</i> colonization in patients affected with CF.
Inclusion Criteria	Patients with CF, older than 1 year and not chronically colonised by <i>Pa</i> (first or intermittent colonization) and with no clinical signs of respiratory exacerbation.
Exclusion criteria	Chronic colonisation by <i>Pa</i> (continuative presence of <i>Pa</i> in the bronchial secretions for more than 6 months), evidence of respiratory exacerbation, which renders treatment with intravenous antibiotics indispensable. Airway infection by <i>Burkholderia cepacia</i> complex.
Methods	Eligible patients will be randomized to one of the two protocols of treatment under study. After a single 1-month therapy cycle with the proposed protocols, there will be an eradication, if 3 sputum samples will be negative for <i>Pa</i> in the six months following the antibiotic treatment. A sequential analysis will be used.
Expected results and anticipated output	To use in the routine an effective antibiotic treatment for <i>Pa</i> eradication.
Start of recruitment	01/02/2008
End of experimental plan	31/01/2011
Publication on medical Journal	31/12/2011