Examples of Preliminary Research

**Study documentation system with electronic connection to a laboratory**

Since 2006, the validated study documentation system ClinBase™ has been used in the Department of Clinical Airway Research. All clinical trials are now planned, organized, performed, and monitored by using ClinBase™. Besides project planning tools, ClinBase™ also includes a comprehensive patient database which supports the acquisition of study participants. Furthermore, the existing interfaces to different measuring instruments allow the collected data, such as ECG, blood pressure, or observed clinical signs and symptoms, to be read in directly to ClinBase™.

Another focus of the system is the processing of laboratory samples for evaluation of safety parameters and for the wide range of pharmacokinetic analyses.

A direct data connection to an external routine laboratory is at present being set up, so that investigations can then be ordered electronically, and the test results in turn can be transmitted electronically to ClinBase™, assessed within the system by the study physicians, and stored in the electronic patient record.

**Efficacy comparison of pseudoephedrine plus cetirizine during exposure to grass pollen in a pollen exposure chamber in and out of the pollen season**

Numerous pollen exposure studies have been conducted already at the Fraunhofer ITEM. They have always been scheduled to be performed out of the pollen season, so as to avoid interaction with the naturally occurring pollen. Whether or not naturally occurring pollen has an impact on the results of pollen exposure studies conducted in the Fraunhofer Environmental Challenge Chamber (ECC) is, as yet, unknown.

In an ongoing randomized, double-blind, placebo-controlled crossover study, 60 patients with seasonal allergic rhinitis are challenged with grass pollen in the Fraunhofer ECC during the grass pollen season. After 2 hours, the patients receive either a combination therapy consisting of 10 mg cetirizine plus 120 mg pseudoephedrine, or placebo. The patients are not allowed to undergo any other anti-allergic therapy during the pollen season.

In the subsequent second part of the study, the patients are again exposed two times for 6 hours each to grass pollen in the Fraunhofer ECC, this time out of the pollen season. As before, patients will be administered the study medication after 2 hours.

The aim of this study is to investigate whether different results are obtained regarding the efficacy of the study medication in and out of the pollen season. If this is not the case, an impact of naturally occurring pollen on the results obtained in the Fraunhofer ECC can be excluded. This would allow future pollen exposure studies to be performed also during the pollen season.

**Investigations into the effects of ultrafine carbon particles on the allergic inflammatory response in the lungs of patients with allergic asthma**

The percentage of ultrafine particles with respect to the total particle content of the ambient air has been steadily increasing over the past few decades. Epidemiological studies have shown that during periods of elevated ultrafine particle load, asthma patients increasingly exhibit asthmatic symptoms and reduced lung function. These data suggest that patients with allergic asthma respond particularly sensitively to ultrafine particles. Clinical studies investigating the direct effects of ultrafine particles on the allergic inflammation in the lungs of asthmatics, however, have not been reported to date.

In order to gain insights into the effects of ultrafine carbon particles on the allergic inflammation, a randomized, double-blind study is currently being performed at the Fraunhofer ITEM. At intervals of 30 days, 16 patients with seasonal asthma are exposed for 2 hours to artificial ultrafine carbon particles (50 mg/m³) or to particle-free air. Eighteen hours after the exposure, grass pollen is instilled into the lungs during bronchoscopy. Another 24 hours later, a second bronchoscopy is performed including bronchoalveolar lavage to collect cells, allowing for the influx of inflammatory cells to be subsequently investigated in the laboratory.

The results of this controlled study are to provide an answer to the question whether or not ultrafine particles have an impact on allergic inflammation. Getting an answer to this question is a red-hot issue for scientists and health politicians.