Unbiased BIOmarkers for the Prediction of REspiratory Disease Outcomes : understanding severe asthma.

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* To define the characteristics of patients with severe asthma in terms of clinical features, physiology and biomarker profiles and to compare these with patients with mild-moderate asthma, and healthy controls* To repeat the measurement of clinical...

Ethical review	-
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON37938

Source
ToetsingOnline

Brief title
UBIOPRED: understanding severe asthma

Condition

- Respiratory disorders NEC

Synonym
Severe asthma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: EU,Innovative Medicines Initiative (IMI)

Intervention

Keyword: asthma, biomarker, handprint, phenotype

Outcome measures

Primary outcome

The study will assess and integrate multiple parameters in terms of clinical, functional, cellular, molecular and patient reported outcomes for developing phenotype *handprints* of severe asthma. For each parameter a number of endpoints have been selected which

will be used for the following goals:

* The characterization into phenotypic handprints of patients with severe asthma and the comparison of these characteristics with those of mild to moderate asthmatics and healthy controls

* To enable the linking of molecular targets for drug intervention with the pathophysiology of severe asthma

* Based upon the integration of data collected from severe asthma patients, classifiers and predictors will be developed. This will form the basis of the initial phenotype handprint.

Secondary outcome

NA

Study description

Background summary

Severe asthmatics are a heterogeneous patient group with frequent exacerbations and/or progressive airways obstruction despite high levels of therapy.

Development of new treatments for such patients is hampered by heterogeneous pathogenesis, lack of consensus on diagnostic criteria, difficulty in translating pre-clinical human and animal models to drug efficacy and absence of biomarkers that predict therapeutic efficacy.
U-BIOPRED aims to overcome the bottlenecks in drug development for severe asthma by a focused and stepwise strategy based on an unbiased analysis of multi-dimensional invasive and non-invasive biomarkers (phenotype handprints). The use of biomarker profiles comprised of various types of high-dimensional data from severe asthma cohorts and controls, integrated by an innovative systems biology approach into distinct phenotype handprints, will enable significantly better prediction of therapeutic efficacy than single or even clustered biomarkers of one data type, and will identify novel targets.

Study objective

* To define the characteristics of patients with severe asthma in terms of clinical features, physiology and biomarker profiles and to compare these with patients with mild-moderate asthma, and healthy controls
* To repeat the measurement of clinical variables and biomarker profiles during longitudinal follow up of the severe asthma cohorts, including during severe exacerbations, and to compare these to baseline measures
* To use the baseline and longitudinal characteristics to determine phenotype handprints by combining high dimensional datasets using a systems biology approach
* To develop phenotype handprints which will enable improved clinical understanding and which will be used to determine clinical progression and efficacy of interventions

Study design

Multi-centre prospective observational study

Study burden and risks

The burden associated with this study includes several visits, during which an intake interview, a physical examination, lung function tests will be done. Bronchoscopy and nasal brushes are optional for subjects. In our own experience as well as based on literature this is well tolerated by as well mild asthmatics as patients with moderate to severe asthma.
The patients themselves will not benefit directly from this investigation. However, the group of asthmatic patients may benefit from this study in the future. Severe asthmatics are a heterogeneous patient group with frequent exacerbations and/or progressive airways obstruction despite high levels of therapy. Development of new treatments for such patients is hampered by heterogeneous pathogenesis, lack of consensus on diagnostic criteria, of biomarkers that predict therapeutic efficacy.

U-BIOPRED aims to overcome the bottlenecks in drug development for severe asthma.
As such, we consider the balance between risks and discomfort for the patients (low) and the possible benefit for these patient groups in the future (potentially high) acceptable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Able to give written informed consent prior to participation in the study, which includes ability
to comply with the requirements and restrictions listed in the consent form. Informed consent must be obtained prior to undertaking any study procedures.
2. Male or female subject aged 18 years or older at screening.

3. Able to complete the study and all measurements.
4. Able to read, comprehend, and write at a sufficient level to complete study related materials.;The additional in- and exclusion criteria for all cohorts are mentioned on page 28-34 of the protocol.

Exclusion criteria

1. As a result of medical interview, physical examination or screening investigation the physician responsible considers the subject unfit for the study either because of the risk to the patient due to the study or the influence this may have on the study results.
2. The subject has a history of drug or other allergy, which, in the opinion of the responsible physician, contra-indicates their participation.
3. Subject is female who is pregnant or lactating or up to 6 weeks post partum or 6 weeks cessation of breast feeding.
4. The subject has participated within 3 months of the first dose in a study using a new molecular
entity, or the first dose in any other study investigating drugs or having participated within three
months in a study with invasive procedures. Any U-BIOPRED assessments should be deferred until 3 months after the first dose or invasive procedure. Permission from the Scientific Board must be obtained to enroll or allow the continued participation of a subject enrolled in another
study.
5. Those who, in the opinion of the investigator, have a risk of non-compliance with study procedures.
6. The subject has a recent history of incapacitating psychiatric disorders
7. History or current evidence of an upper or lower respiratory infection or symptoms (including common cold) within 2 weeks of baseline assessments (assessments should be deferred).;The additional in- and exclusion criteria for all cohorts are mentioned on page 28-34 of the protocol.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2011
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO

Date:	10-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL32361.018.10