

ATHMOS - Validation of the ACT questionnaire in general practice

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General

Identification

Detailed name Validation of the ACT questionnaire in general practice

Sign or acronym ATHMOS

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL n°90 60 78 (12/05/2006)

General Aspects

Medical area Pneumology

Others (details) Asthma

Keywords asthma, control, "Asthma Control Test ©" (ACT)

Scientific investigator(s) (Contact)

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Unit Laboratoire GSK

Collaborations

Funding

Funding status Private

Details GSK laboratory

Governance of the database

Sponsor(s) or organisation(s) responsible Laboratoire GSK

Organisation status Private

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

Database recruitment is carried out by an intermediary A selection of health care professionals
An administrative base or a register

Database recruitment is carried out as part of an interventional study No

Additional information regarding sample selection.

Selection of GP:

A pre-selection via random drawing will be established using a CEGEDIM file of general practitioners.

The general practitioners pre-selected through the random drawing will receive a mailing which will briefly present the objectives of the study and how it will unfold. It will include a postage-paid response card to be returned to the logistics center indicating whether or not the practitioner wants to participate in the study

A telephone call to confirm participation will be made to the first 1000 general practitioners who have agreed

Selection of pneumologists:

A pre-selection via random drawing will be established using a CEGEDIM file of pneumologist/allergy doctors.

The pre-selected pneumologists/allergy doctors will be contacted by telephone (brief presentation of the objectives and the unfolding of the study) in the order of the preselection until the number of pneumologists/allergy doctors accepting to participate reaches 500.

The patients will be included after they have read the patient information letter

Database objective

| | |
|--------------------|--|
| Main objective | Describe in actual practice the level of control of asthma using the ACT questionnaire (Asthma Control Test) |
| Inclusion criteria | Male or female aged 18 years or older Patient having asthma diagnosed at least 12 months ago Patient informed of the objectives of the study and accepting the collection and the analysis of the data concerning him. |

Population type

| | |
|-----|---|
| Age | Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more) |
|-----|---|

| | |
|--------------------|-----------------|
| Population covered | Sick population |
|--------------------|-----------------|

| | |
|--------|---------------|
| Gender | Male Woman |
|--------|---------------|

| | |
|----------------|----------|
| Geography area | National |
|----------------|----------|

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|------------------------------|--------|
| Detail of the geography area | France |
|------------------------------|--------|

Data collection

Dates

| | |
|--|------|
| Date of first collection (YYYY or MM/YYYY) | 2006 |
|--|------|

| | |
|---|------|
| Date of last collection (YYYY or MM/YYYY) | 2008 |
|---|------|

Size of the database

| | |
|--|---------------------------|
| Size of the database (number of individuals) | [1000-10 000[individuals |
|--|---------------------------|

| | |
|--------------------------------------|------|
| Details of the number of individuals | 2362 |
|--------------------------------------|------|

Data

| | |
|-------------------|---------------------------|
| Database activity | Data collection completed |
|-------------------|---------------------------|

| | |
|------------------------|-----------------------------------|
| Type of data collected | Clinical data Declarative data |
|------------------------|-----------------------------------|

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|---|--|
| Clinical data (detail) | Direct physical measures Medical registration |
| Declarative data (detail) | Paper self-questionnaire |
| Presence of a biobank | No |
| Health parameters studied | Health care consumption and services Quality of life/health perception |
| Care consumption (detail) | Hospitalization Medical/paramedical consultation Medicines consumption |
| Procedures | |
| Data collection method | The physician will complete the medical questionnaire for inclusion and will give the inclusion self-questionnaire to the patient. During the 3-month inclusion period, the investigating physicians must collect in a data register patients who are not included in the cohort, that meet the eligibility criteria but who cannot or do not want to participate in the study. The patients included will be examined again at the next spontaneous consultation which will also be a follow-up visit within the framework of the study where a follow-up questionnaire will be completed by the investigator and a follow-up self-questionnaire will be given to the patient |
| Participant monitoring | Yes |
| Details on monitoring of participants | spontaneous consultation following the inclusion during which will be completed a medical follow-up questionnaire and a follow-up self-questionnaire |
| Links to administrative sources | No |
| Promotion and access | |
| Promotion | |
| Access | |
| Terms of data access (charter for data provision, format of data, availability delay) | Publications in progress |
| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |

