

# TARC-ABPA - Study of Th2/Th17 balance during allergic bronchopulmonary aspergillosis

Head :Magnan Antoine, L'INSTITUT DU THORAX - INSERM UMR1087 / CNRS UMR 6291

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## General

### Identification

Detailed name Study of Th2/Th17 balance during allergic bronchopulmonary aspergillosis

Sign or acronym TARC-ABPA

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CPP n° 2012-R6 03/2013 ; Afsapps

### General Aspects

Medical area Pneumology  
Study of allergies

Health determinants Genetic

Keywords allergic bronchopulmonary aspergillosis, exacerbations, biomarkers

### Scientific investigator(s) (Contact)

Name of the director Magnan

Surname Antoine

Address 44000 NANTES

Phone + 33 (0)2 28 08 01 26

Email antoine.magnan@univ-nantes.fr

Unit L'INSTITUT DU THORAX - INSERM UMR1087 / CNRS UMR 6291

Organization INSERM / CHU DE

### Collaborations

| Funding                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Funding status                                                         | Mixed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Details                                                                | DRASS PAYS DE LA LOIRE IRSR pays de loire                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Governance of the database                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Sponsor(s) or organisation(s) responsible                              | CHU DE NANTES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Organisation status                                                    | Public                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Additional contact                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Main features                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Type of database                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Type of database                                                       | Study databases                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Study databases (details)                                              | Cohort study                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Database recruitment is carried out by an intermediary                 | A selection of health institutions and services                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Database recruitment is carried out as part of an interventional study | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Details                                                                | Performed at individual level                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Additional information regarding sample selection.                     | Perspective cohort. End of inclusions: 01/06/2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Database objective                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Main objective                                                         | Evaluate the relevance of new biomarkers for monitoring allergic bronchopulmonary aspergillosis : study of changes in exhaled NO, induced sputum cellularity, Aspergillus serology by ELISA method lymphocyte populations.                                                                                                                                                                                                                                                                                                          |
| Inclusion criteria                                                     | ABPA diagnostic: total IgE superior to 417 KU/L<br>immediat hypersensitivity to Aspergillus (positive prick-test and/or positive specifics ige) proximal DDB (bronchiectasis) and/or labile infiltrate (ABPA-S) positives anti-aspergillosis precipitins.<br>Patients pre-included : legally adults, either gender; members of a social security system, obligatory informed and written consent, carriers of an ABPA with all the criteria set out hereinafter, at least once in their medical file; patients without exacerbation |

since V0 or V0', allowing the definition of a basic status.

| Population type                              |                                                                                        |
|----------------------------------------------|----------------------------------------------------------------------------------------|
| Age                                          | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years) |
| Population covered                           | Sick population                                                                        |
| Gender                                       | Male<br>Woman                                                                          |
| Geography area                               | Regional                                                                               |
| French regions covered by the database       | Pays de la Loire                                                                       |
| Detail of the geography area                 | French Multicentric cohort (3 centers) : Nantes, Angers, Le Mans                       |
| Data collection                              |                                                                                        |
| Dates                                        |                                                                                        |
| Date of first collection (YYYY or MM/YYYY)   | 06/2012                                                                                |
| Date of last collection (YYYY or MM/YYYY)    | 06/2014                                                                                |
| Size of the database                         |                                                                                        |
| Size of the database (number of individuals) | < 500 individuals                                                                      |
| Details of the number of individuals         | 30                                                                                     |
| Data                                         |                                                                                        |
| Database activity                            | Current data collection                                                                |
| Type of data collected                       | Clinical data<br>Declarative data<br>Biological data                                   |
| Clinical data (detail)                       | Direct physical measures<br>Medical registration                                       |
| Declarative data (detail)                    | Face to face interview                                                                 |

|                                                                                       |                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Biological data (detail)                                                              | At each exam: induced expectoration (only at the Nantes center), blood sample (improved total IgE test, specifics, IgC?)ECBC                                                                                                                    |
| Presence of a biobank                                                                 | Yes                                                                                                                                                                                                                                             |
| Contents of biobank                                                                   | Serum<br>Blood cells isolated<br>DNA<br>DNAc/RNAm                                                                                                                                                                                               |
| Details of biobank content                                                            | Serum, blood cells, DNA, RNA bank                                                                                                                                                                                                               |
| Health parameters studied                                                             | Health event/morbidity                                                                                                                                                                                                                          |
| <b>Procedures</b>                                                                     |                                                                                                                                                                                                                                                 |
| Data collection method                                                                | Self-questionnaire : manually filled paper questionnaire with double data entry. Interviews: entry from a paper form (manually filled) with double entry. Clinical examinations : direct entry<br>Biological examinations direct computer entry |
| Participant monitoring                                                                | Yes                                                                                                                                                                                                                                             |
| Details on monitoring of participants                                                 | Follow-up duration : 2 years                                                                                                                                                                                                                    |
| Links to administrative sources                                                       | No                                                                                                                                                                                                                                              |
| <b>Promotion and access</b>                                                           |                                                                                                                                                                                                                                                 |
| <b>Promotion</b>                                                                      |                                                                                                                                                                                                                                                 |
| <b>Access</b>                                                                         |                                                                                                                                                                                                                                                 |
| Terms of data access (charter for data provision, format of data, availability delay) | Data utilization by academic teams te be determined. Data utilization not available for industry sectors.                                                                                                                                       |
| Access to aggregated data                                                             | Access on specific project only                                                                                                                                                                                                                 |
| Access to individual data                                                             | Access on specific project only                                                                                                                                                                                                                 |