

# Foetal programming of allergic diseases

<b>Submission date</b> 06/11/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/04/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/03/2016	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

An allergy is a reaction the body has to a particular food or substance. The aim of this study is to find out whether endocrine (hormone) and immune system alterations and nutrition during pregnancy influence the child's risk of developing an allergic disease.

### Who can participate?

Women aged between 18 - 35 with a single-child pregnancy (gestational age 8 - 12 weeks)

### What does the study involve?

The participants' medical, obstetrical and gynaecological history is thoroughly documented, and sociodemographic data (including smoking habits of pregnant mother and her partner) is collected. In addition, a stress evaluation is performed using questionnaires. Living conditions (including smoking habits, work life, vaginal infections, housing, decorating activities, etc) are investigated using a questionnaire. Blood samples are taken from the prospective mothers and analysed. A second visit is arranged at a gestational age of 20 - 24 weeks, when a regular pregnancy check-up is also scheduled. Here, the psychological evaluation is repeated and the living conditions are again documented. In addition, the women are asked to fill out a questionnaire on dietary habits over the past 3 months. Blood samples are taken again and analysed. The women are asked to return a postage-paid pregnancy outcome card to us once their baby is born. A year after birth, the children are invited for a clinical visit at our study centres. Here we examine the children for clinical symptoms of atopic dermatitis (a skin condition). Then, once every year, in the month of the child's birthday, a questionnaire is mailed to the parents to document the incidence of allergic diseases in the child. Detailed information is requested on the child's vaccination history, presence of in-house pets or smokers, upbringing in urban or rural environment. This thorough documentation is repeated until the child is five years old.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Charité, Campus Virchow Klinikum (Germany)

When is the study starting and how long is it expected to run for?

October 2009 to October 2017

Who is funding the study?

German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

Who is the main contact?

Dr Maike Pincus

## Contact information

### Type(s)

Scientific

### Contact name

Dr Maike Pincus

### Contact details

Charité, Campus Virchow Klinikum

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## Additional identifiers

### Protocol serial number

PI 877/1-1

## Study information

### Scientific Title

Foetal Programming of Allergic Diseases: an observational multicentre pregnancy cohort study

### Acronym

FePAD

### Study objectives

Endocrine and immune alterations as well as nutrition during pregnancy influences the individual risk for the child to develop an allergic disease.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Charite, Campus Virchow Klinikum Ethikkommission (Germany), 16/05/2006 and 04/11/2008, ref: EA2/030/06

2. St. Joseph's Research Ethics Board (Canada), 20/12/2007, ref: 07-2929

**Study design**

Observational multicentre cohort study

**Primary study design**

Observational

**Study type(s)**

Screening

**Health condition(s) or problem(s) studied**

Allergic diseases, e.g., atopic dermatitis, asthma and allergic rhinoconjunctivitis

**Interventions**

After written informed consent, the medical, obstetrical and gynaecological history will be thoroughly documented, and sociodemographic data (including smoking habits of pregnant mother and her partner) will be collected. In addition, stress evaluation will be performed employing standardised questionnaires on psychosocial and emotional functioning. Here, validated questionnaires will be employed. Living conditions (including smoking habits, work life, vaginal infections, housing, decorating activities, etc.) will be investigated by a published and validated questionnaire.

Further, blood will be drawn from the prospective mothers and analysed with respect to the endocrine-immune profile.

A second visit is envisaged at a gestational age of 20 - 24 weeks, where a regular pregnancy check up is also scheduled. Here, the psychometric evaluation will be repeated and the living conditions will again be documented. In addition, the women will be asked to fill out an established questionnaire on dietary habits over the past 3 months. Furthermore, blood will be drawn again and endocrine-immune parameters will be analysed.

For the follow-up after birth, a postage-paid pregnancy outcome card will be placed in the pregnancy pass. The women will be asked to return this card to us once their baby is born. A year after birth, the children will be invited for a clinical visit at our study centres. Here we will examine the children for clinical symptoms of atopic dermatitis and scoring the symptoms with a clinical score.

Then, once every year, in the month of the child's birthday, a questionnaire will be mailed to the parents to document the incidence of allergic diseases in the child. Further, detailed information on the child's vaccination history, presence of in-house pets or smokers, upbringing in urban or rural environment will be requested. This thorough documentation is planned to be repeated until the child is five years old.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Evaluation of environmental cues as further potential risk factors during pregnancy (e.g. living conditions, smoking habits, perceived stress, social support and nutrition) for the child's risk to develop an atopic disease.

### **Key secondary outcome(s)**

Investigation of potential mechanism, by which environmental cues may exert a foetal programming effect towards allergic diseases during pregnancy. Here we will concentrate on endocrine, immune and neurobiological mechanisms.

### **Completion date**

01/10/2017

## **Eligibility**

### **Key inclusion criteria**

1. Pregnant women recruited at a gestational age of 8 - 12 weeks
2. Aged between 18 and 35 years old
3. Single child pregnancy
4. Full-term deliveries

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Female

### **Key exclusion criteria**

1. Fertility treatments and infections (human immunodeficiency virus [HIV], hepatitis B and C)
2. A history of recurrent spontaneous abortion, pre-eclampsia, or gestational diabetes in previous pregnancies
3. Sufferers of the following chronic diseases:
  - 3.1. Inflammatory bowel diseases
  - 3.2. Diabetes type 1
  - 3.3. Rheumatoid and autoimmune diseases
  - 3.4. Previous chemotherapies and radiation therapies

### **Date of first enrolment**

01/10/2009

### **Date of final enrolment**

01/10/2017

## Locations

### Countries of recruitment

Canada

Germany

### Study participating centre

Charité, Campus Virchow Klinikum

Berlin

Germany

13353

## Sponsor information

### Organisation

Individual sponsor (Germany)

## Funder(s)

### Funder type

Research council

### Funder Name

Deutsche Forschungsgemeinschaft

### Alternative Name(s)

German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Germany

# Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary