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Foetal programming of allergic diseases

Submission date	Recruitment status	[X] Prospectively registered
06/11/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/04/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/03/2016	Injury, Occupational Diseases, Poisoning	[ ] 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
Klinik fuer Paediatrie mit Schwerpunkt Pneumologie und Immunologie
Augustenburger Platz 1
Berlin
Germany
13353

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Ethikkomission (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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Allergic diseases, e.g., atopic dermatitis, asthma and allergic rhinoconjuncitvitis

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/10/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1300

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)

Sponsor details
Dr Maike Pincus
Charité, Campus Virchow Klinikum
Klinik fuer Paediatrie mit Schwerpunkt Pneumologie und Immunologie
Augustenburger Platz 1
Berlin
Germany
D-13353

Sponsor type
Other

Funder(s)

Funder type
Research council

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration