

PACT: Prevention of Atopy among Children in Trondheim

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| Submission date 01/12/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 08/01/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 13/11/2013 | Condition category Signs and Symptoms | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.pact.no>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A controlled, population-based intervention study for the Prevention of Atopy among Children in Trondheim

Acronym

PACT

Study objectives

The primary objective of the PACT trial is to study the efficacy of an intervention on three assumed risk factors for atopic disease (AD), asthma, and allergic rhinoconjunctivitis (ARC) in an unselected population of pregnant women and small children. Further, to study the effectiveness of intervening on these risk factors on the incidence of asthma and allergic disease.

1. Omega-3 fatty acid intake
2. Second hand smoke (SHS) exposure
3. Indoor dampness

The prospective structure and longevity of the PACT study enables etiological studies as well as prospective and nested case-cohort studies, and controlled clinical trials. Accordingly, three sub-studies, and an end-point study, were designed.

Publications under review (at time of registration)

1. Dotterud CK, Storro O, Johnsen R., Oien T. Probiotics in non-selected pregnant women in prevention of allergic disease: a randomised, double-blind, placebo-controlled trial. J Allergy Clin Immun. Under review June 2009.
2. Smidesang I, Saunes M, Storro O, Øien T, Holmen TL, Johnsen R. et al. Allergy related disorders among 2-year olds in a general population. The PACT study. Pediatric Allergy and Immunology. Under review June 2009.

Further reading:

2007 results of the Young-Hunt study on psychological morbidity in adolescents with atopic dermatitis in <http://www.ncbi.nlm.nih.gov/pubmed/17223868>

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved by the Regional Committee for Research Ethics in Middle Norway, 15/08/2000, ref: 120-2000
2. The Norwegian Data Inspectorate (ref: 2003/953-3 KBE/-) and the Probiotic study is registered in ClinicalTrials.gov (identifier NCT00159523)

Study design

Prospective controlled population-based intervention study

Primary study design

Interventional

Secondary study design

Other

Study setting(s)

Other

Study type(s)

Prevention

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

Atopic and allergic diseases in early childhood; atopic eczema; allergic rhinoconjunctivitis; asthma

Interventions

1. Increased omega-3- fatty acid intake in pregnancy and for children up to 2 years of age.
2. Reduced smoking behaviour and smoking cessation in pregnancy, reduced second hand smoke (SHS) exposure for mother and child after birth, smoking relapse prevention.
3. Reduced indoor dampness exposure

The interventions continue in all scheduled contacts with GPs, maternity care nurses and midwives throughout the study period from early pregnancy until the child is 2 years of age. This schedule is incorporated as the recommended follow-up for all pregnant women in the community in the intervention period.

Brochures with information for participants were delivered at inclusion with updates at relevant contacts at 6 weeks postnatal, 1 year and 2 years after birth.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Self-reported changes in risk factor exposure and behaviour reported in repeated questionnaires in pregnancy, 6 weeks postnatal and at 1 and 2 and 6 years after birth

Secondary outcome measures

Changes in prevalence of atopic disease when the child was 2 years of age and 6 years of age

Overall study start date

01/09/2000

Completion date

31/12/2011

Eligibility

Key inclusion criteria

All pregnant women living in the community of Trondheim, Norway willing to complete repeated questionnaires on risk factors and disease during pregnancy and until their child was 6 years of age could be included in the study

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

14000

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/09/2000

Date of final enrolment

31/12/2011

Locations**Countries of recruitment**

Norway

Study participating centre

ISM, NTNU

Trondheim

Norway

N-7489

Sponsor information**Organisation**

Norwegian University of Science and Technology (Norway)

Sponsor details

Department of Community Medicine and general Practice

MTFS

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Sponsor type
University/education

ROR
<https://ror.org/05xg72x27>

Funder(s)

Funder type
Government

Funder Name
Norwegian Department of Health and Social affairs (Norway) - (1997-2003)

Funder Name
AstraZeneca Norge AS (Norway) - Control cohort funding (2000-2001)

Funder Name
Norwegian University of Science and Technology (Norges Teknisk-Naturvitenskapelige Universitet [NTNU]) (Norway) - Research fellow scholarship (1999-2003)

Funder Name
Norwegian Research Council (Norway) - Research fellow scholarship (1999-2003)

Funder Name
Norwegian Medical Association (Norway) - Grant (1999)

Funder Name
SINTEF Unimed (Norway) - Grant (1999)

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---|--------------|------------|----------------|-----------------|
| Results article | results on atopic dermatitis in 2-year olds | 01/01/2008 | | Yes | No |
| Results article | results on assessing atopic disease in 2-6 year olds | 01/09/2008 | | Yes | No |
| Results article | results on maternal smoking cessation during pregnancy and child weight | 01/01/2009 | | Yes | No |
| Results article | results on early intake of fish oils for prevention | 01/02/2010 | | Yes | No |
| Results article | results on minimal smoking intervention for pregnant women and their partners | 01/02/2010 | | Yes | No |
| Results article | results | 28/07/2010 | | Yes | No |
| Results article | results | 20/05/2011 | | Yes | No |
| Results article | allergy test substudy results | 01/03/2012 | | Yes | No |
| Results article | asthma results | 24/10/2012 | | Yes | No |
| Results article | bifidobacteria results | 01/01/2013 | | Yes | No |
| Results article | results | 08/02/2013 | | Yes | No |