

PACT: Prevention of Atopy among Children in Trondheim

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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes