

Prophylaxis of atopic and allergic manifestations and activation or modulation of the immune system by Pro-Symbioflor® treatment in newborns / small children from atopically pre-disposed parents.

Submission date 21/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/09/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 13/11/2013	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.allergie-centrum-charite.de/index.php?id=1105>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Prophylaxis by Pro-Symbioflor® of atopic and allergic manifestations and activation or modulation of the immune system in newborns / small children from atopically pre-disposed parents. Prospective, randomized, placebo-controlled, double-blind parallel group trial in 632 healthy newborns aged 4 weeks with increased risk for atopic dermatitis with repeated application of Pro-Symbioflor® t.i.d or placebo between 2 and 7 months of age and an observation period until the age of 3 years.

Acronym

PAPS

Study objectives

Pro-Symbioflor® is an immunologically active product containing components of a mixture of Escherichia coli (gram negative) and Enterococcus faecalis (gram positive).

Pro-Symbioflor® is claimed to be effective as an immunomodulatory acting drug in the primary prevention of atopic dermatitis and other allergic diseases. To prove this, a trial was designed to test for the Verum - Placebo superiority in the preventive efficacy lowering the risk to develop an atopic disease under a 6 months lasting prophylactic treatment with Pro-Symbioflor® in newborns/ small children aged between 4 weeks and 3 years. In addition its immunomodulatory effects were to be studied.

Null hypothesis H0: The risk of a manifestation of atopic dermatitis (AD) under treatment verum or placebo is not different. Alternative hypothesis H1: The risk of a manifestation of AD under treatment with verum is twice as low as under placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. The independent ethics committee (IEC) at Charité approved on the 2nd of March 2002 (ref: 19 /2002)
2. Intermediate evaluation of the study (half of cases completed) was carried out and approval to continue granted on the 21st of October 2005
3. Amendment to the protocol approved on the 7th of March 2007

Study design

Prospective randomised placebo controlled double blind parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Atopic dermatitis

Interventions

1. Intervention group:

Pro-Symbioflor® (verum): Bacterial lysate manufactured from $1,5 \times 10^8$ Enterococcus faecalis (DSM 16440) and $1,5 \times 10^8$ Escherichia coli (DSM 17252). 3x5 drops per day for 2 weeks then increased to 3x10 drops per day between 2 and 7 months of age.

2. Control group:

Pro-Symbioflor® (placebo): Culture medium without bacteria. 3x5 drops daily, for 2 weeks increased to 3x10 drops daily between 2 and 7 months of age.

The total duration of follow up will be 3 years.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Incidence of atopic dermatitis during the treatment phase between the 4th and 31st life week under the prophylaxis with verum or placebo.

Secondary outcome measures

1. Incidence of atopic dermatitis after treatment and until end of 3 years
2. Time until the first manifestation of an AD
3. Severity of AD at manifestation of an eczema: SCORing Atopic Dermatitis (SCORAD) Score
4. Frequency and time until the appearance as well as severity of allergic/atopic manifestations in the gastrointestinal tract
5. Frequency and until the appearance as well as severity of an allergic/atopic manifestation in the airways
6. Frequency of a sensitization against food allergens
7. Induction / enhancement of a Th1-immune response
8. Toll-like-receptors
9. Safety pharmacological Investigations before and at the end of the treatment as well as the observation period
10. Adverse events

Overall study start date

28/05/2002

Completion date

19/09/2010

Eligibility

Key inclusion criteria

1. Healthy male and female newborns aged 4 weeks
2. Regularly developed newborns - body weight: ≥ 2500 g; gestational age $> 37+0$ weeks
3. No relevant illnesses since the birth (except transient Hyperbilirubinemia)
4. Positive atopic anamnesis with at least one parent (atopic dermatitis, bronchial asthma, allergic rhino-conjunctivitis)
5. Written informed consent by the parents as the legal representatives

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

632

Key exclusion criteria

1. Diseases that require immunosuppressive therapy (systemic administration of steroids or cyclosporine A)
2. Transfer to an intensive care unit after birth
3. Known immune disturbances or defects (Lymphopenia, Thrombopenia)
4. Concomitant medication or treatment (except for prophylaxis)
5. Inadequate ability or willingness of the parents to communicate or to cooperate
6. Family anamnesis of a congenital deficiency in immune defence

Date of first enrolment

28/05/2002

Date of final enrolment

19/09/2010

Locations

Countries of recruitment

Germany

Study participating centre
Department of Pediatric Pneumology and Immunology
Berlin
Germany
13353

Sponsor information

Organisation
SymbioPharm GmbH (Germany)

Sponsor details
Auf den Luppen 8
Herborn
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35745
kurt.zimmermann@symbio.de

Sponsor type
Industry

Website
<http://www.symbiopharm.de>

ROR
<https://ror.org/03d8m2k26>

Funder(s)

Funder type
Industry

Funder Name
Symbiopharm GmbH (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2013		Yes	No