A Randomised, Double-Blind, Placebo-controlled, 32-week, Phase IIa trial to investigate the efficacy of OM-85 versus matched placebo in reducing disease severity in children aged 3 to 24 months with early clinical diagnosis of moderate atopic dermatitis

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Primary Objective Primary objective is to assess the efficacy of OM-85 versus matched placebo in children with moderate AD in reducing disease severity over the first 16 weeks and the first 24 weeks of the treatment period.Secondary Objectives...

Ethical review	Approved WMO
Status	Completed
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON54004

Source
ToetsingOnline

Brief title
Immunomodulation by OM-85 in early AD

Condition

- Epidermal and dermal conditions

Synonym
Atopic dermatitis, Neurodermitis

Research involving
Human

Sponsors and support

Primary sponsor: OM Pharma
Source(s) of monetary or material Support: OM Pharma

Intervention

Keyword: Atopic Dermatitis, Children, Moderate

Outcome measures

Primary outcome

Primary Endpoints:

- Weekly area under the curve (AUC) of the EASI score from baseline up to the latest evaluable assessment before or on week 16 visit, use of rescue medication, loss to follow-up or withdrawal of consent, whichever occurs first

- Weekly area under the curve (AUC) of the EASI score from baseline up to the latest evaluable assessment before or on week 24 visit, use of rescue medication, loss to follow-up or withdrawal of consent, whichever occurs first

Secondary outcome

- Time to new AD flare, defined as >= 50% worsening of Baseline EASI score or EASI score of > 21.0 (severe AD) from Baseline to end of the treatment period and to the end of the observational period

- Percentage of patients free of flares from Baseline to the end of treatment

period

- Difference in free of flares days between treatment groups (placebo vs. verum) from Baseline to the end of treatment period

- Time to new AD flare, defined as >= 50% worsening of Baseline EASI score or EASI score of > 21.0 (severe AD) from Baseline to end of the treatment period and the observational period

- Percentage of patients free of flares from Baseline to the end of treatment period

- Difference in free of flares days between treatment groups (placebo vs. verum) from Baseline to the end of treatment period

- Number of new AD flares during the induction and maintenance period and during whole treatment and observational period

- Weekly AUC of the EASI score from Baseline to the end of the treatment period

- Weekly AUC of the EASI score from Baseline to the end of the observational period

- EASI score change during the induction and maintenance period and during the whole treatment period and the observational period

- SCORAD score change during the induction and maintenance period and during the whole treatment period and the observational period

- vIGA-AD score change during the induction and maintenance period and during the whole treatment period and the observational period

- ADCT score change during the induction and maintenance period and during the whole treatment period and the observational period

- Number and duration in days of TCS treatments for acute flares during the

induction and maintenance period and during the whole treatment

period and the observational period

- Incidence of skin infections requiring systemic treatment and antibiotics

during the induction and maintenance period and during the whole

treatment period and the observational period

- Number of respiratory tract infections and wheezing episodes during the

induction and maintenance period and during the whole treatment

period and during the observational period

Study description

Background summary

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin condition with prominent itching which occurs most frequently in children but also in adults. AD affects up to 20% of children and 10% of adults in high-income countries. AD starts in early childhood during the first 6 months of life in 45% of children, in 60% during the first year of life and before the age of 5 years in at least 85% of affected individuals.
AD has a complex pathophysiology which includes a skewed response towards Th2 immunity, and defects in the innate immune system. The emergence of filaggrin gene (FLG) as a risk allele for atopic disease also shifted weight on the role of the skin barrier in AD pathogenesis. Although AD runs in families, it is impossible to explain the increased prevalence of AD with genetics alone. Factors predisposing to AD may be smaller family size, urban settings, and Western diet, which affect both the skin and gut microbiota. The microbiome has a well-documented role in AD. The crucial interaction between flora and humans in AD is best presented through the hygiene hypothesis [4]. This theory implicates that, in modern sanitized living conditions, there is reduced microbial exposure early in life, which results in inadequate immune priming. A normal child*s early microbiota has protective influence on the immune system from allergic over-sensitization. In contrast, poor development or imbalance of the microbiome early in life is known to affect the cutaneous immune response in a way that children are predisposed to a number of immune conditions, such as AD, with frequent secondary skin infections. Therefore, it is an approach to use treatments based on the stimulation of the immune system by derivatives mimicking the effect of bacteria, viruses or parasites as substitute for the

protective role of infections.

Study objective

Primary Objective
Primary objective is to assess the efficacy of OM-85 versus matched placebo in children with moderate AD in reducing disease severity over the first 16 weeks and the first 24 weeks of the treatment period.

Secondary Objectives

Secondary objectives of the trial are:

To assess the efficacy of OM-85 versus matched placebo in reducing flares over the treatment period and up to the end of the observational periods
To assess the efficacy of OM-85 versus matched placebo in reducing disease severity up to the end of the observational period
To evaluate the efficacy of OM-85 versus matched placebo in reducing the use of co-medications for the treatment of AD
To assess the efficacy of OM-85 versus matched placebo in reducing respiratory tract infections ((RTI) and wheezing episodes over the treatment period and up to the end of the observational period

Exploratory Objectives

Exploratory objectives of the trial are:

To explore the immunomodulatory effects of OM-85 versus matched placebo at the skin and systemic level
To evaluate skin lesions and skin/gut microbiomes, incl. skin S. aureus infections
To assess potential correlations between gut / skin microbiomes and primary and/or secondary outcomes (e.g., EASI, SCORAD, vIGA-AD)
To explore potential correlations between gut microbiome and skin microbiome
To assess the effect of OM-85 versus matched placebo on allergic sensitisation

Safety Objectives

The safety objective is to assess the safety of OM-85 versus matched placebo in early moderate paediatric AD

Study design

This is a Randomised, Double-Blind, Placebo-controlled, 32-week, Phase IIa trial

Intervention

One group receives study medication (OM-85; Broncho-Vaxom), one tablet daily, the other group receives Placebo to OM-85, one tablet daily

Study burden and risks

This study benefits all children suffering from Atopic Dermatitis, as Atopic Dermatitis affects up to 20% of children.
Participating children may receive an improvement of their Atopic Dermatitis.
The trial is designed in a way to keep the burden for participating children as low as possible.
The medicinal product is on the market in several European countries for about 40 years and has proven to be safe in this time..

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. Children of either gender, aged 3 to 24 months
2. Clinically confirmed diagnosis of AD of moderate severity documented by the Investigator and lesions covering up to 30% of the body
3. AD onset no longer than 12 months before screening
4. Legally acceptable representatives (i.e. parent(s) or guardians) of subject according to local regulations have provided the appropriate written informed consent. Written informed consent must be provided before any study-specific procedures are performed including Screening procedures.

Exclusion criteria

1. Any diseases that may be considered as the differential diagnosis of atopic dermatitis, and notably skin infections and infestations (e.g. scabies), other inflammatory skin conditions, dermatological malignancies, dermatological genetic diseases such as immunodeficiency conditions, and nutritional disorders with cutaneous manifestations and drug eruptions.
2. Specifically, any inflammatory skin conditions that are considered during the differential diagnosis of atopic dermatitis: allergic contact dermatitis, dermatographism, psoriasis, pityriasis alba.
3. Any chronic diseases (other than wheezing and asthmatic bronchitis) that require the administration of systemic corticosteroids (e.g., eosinophilic esophagitis) or immunosuppressant agents.
4. Significant medical condition(s), which, in the Investigator*s opinion, are anticipated to require major surgery during the study, or any other type of disorder that might involve an increased risk to the subject, could interfere with study assessments or outcomes, or the ability of parents to comply with the study procedures (e.g. eDiary).
5. Children with known allergy or previous intolerance/sensitivity to any of the trial treatments (IMP, AxMP or standardized emollient) to be administered.
6. Use of systemic drugs interfering with the immune system (e.g. corticosteroids, immunosuppressants) within 30 days before Baseline (with exception of routine vaccinations)
7. Previous or ongoing treatment with other bacterial lysates and/or probiotics within 30 days before Baseline
8. Use of systemic antibiotics within 30 days before Baseline
9. Participation in any other investigational trial on a medical device or medicinal product < 30 days prior to Baseline or any previous participation in a study involving bacterial lysates and/or probiotics, or current treatment with other investigational agent(s)
10. Any major surgery within the last 3 months prior to Baseline, that in the opinion of the Investigator, would not allow safe completion of the clinical study.

11. Subject's families expected to relocate out of study area during the duration of the study.
12. Other household members have previously been randomised in this clinical study.
13. Previous participation to this study.
14. Close affiliation of subject or parents with the investigational site; e.g. a close
relative of the Investigator, dependent person (e.g. employee or student of the investigational site)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	09-02-2023
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	08-03-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	14-05-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-07-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-08-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-04-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-003179-33-NL
ClinicalTrials.gov	NCT05222516
CCMO	NL79068.078.22