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Effect of SYN-AR on alleviation of grass pollen allergy associated symptoms

Submission date
11/08/2023

Recruitment status
No longer recruiting

Registration date
02/02/2024

Overall study status
Completed

Last Edited
01/02/2024

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The increasing number of people affected by seasonal allergic rhinoconjunctivitis (hay fever) worldwide may be linked to a loss of microbial diversity of the intestinal microbiome (gut bacteria) in those affected. The aim of this study is to evaluate the effect of the SYN-AR supplement in three different compositions on the symptoms of allergic rhinoconjunctivitis due to grass pollen in comparison to a placebo (dummy supplement).

Who can participate?
People aged 18 to 65 years with clinically relevant sensitization to grass pollen and allergic symptoms for at least 2 years

What does the study involve?
Participants with a confirmed allergy history and a positive skin prick test will be exposed to grass pollen in an allergen exposure chamber (baseline measurement) and those with a maximum total symptom score of 6 or more will be randomly allocated to take one of three probiotic microbiome supplement compositions or a placebo for three consecutive days per week for a total of 3 weeks. A post-intervention measurement in the allergen exposure chamber will be done at week 4.

What are the possible benefits and risks of participating?
If receiving one of the probiotic microbiome supplement compositions, participants might experience relief from the allergic symptoms associated with their grass pollen allergy. It has been shown previously that probiotics are a safe, low-side-effect option to alleviate the symptoms of allergies. Possible side effects of the treatment are mild gastrointestinal symptoms such as flatulence, abdominal pain or diarrhoea.
When exposed to grass pollen in the allergen exposure chamber, participants might experience the typical allergic symptoms of rhinoconjunctivitis (e.g., sneezing, rhinorrhoea, teary and itching eyes). All exposures are done under the supervision of a study nurse and, if necessary, medical treatment will be available immediately. Participants have the option to take safety medication (10 mg cetirizine) in the 24 hours after the exposure if symptoms persist. A safety phone call will be made on the day after the exposure.

Where is the study run from?
FUTRUE R&S 2 GmbH (Germany)

When is the study starting and how long is it expected to run for?
June 2022 to December 2022

Who is funding the study?
FUTRUE R&S 2 GmbH (Germany)

Who is the main contact?
David Rietbrock, studienkoordination@synformulas.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SYN-AR-01

Study information

Scientific Title
Investigation of the benefit of SYN-AR, a microbiome supplement in three different compositions, on alleviating allergic symptoms associated with rhinoconjunctivitis due to grass pollen against placebo

Acronym
SYN-AR-01

Study objectives
In individuals with allergic rhinoconjunctivitis due to grass pollen, a significant reduction in clinical symptoms upon exposure to grass pollen can be demonstrated after the use of SYN-AR.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 01/09/2022, Ethik-Kommission der Charité Berlin (Ethics Commission of Charité Berlin) (Charitéplatz 1, Berlin, 10117, Germany; +49 30 450 517 222; ethikkommission@charite.de), ref: ref: EA1/128/22

Study design
Monocentric randomized double-blind three-arm parallel-group placebo-controlled clinical study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Allergic rhinoconjunctivitis caused by grass pollen

Interventions
Treatment: three capsules (oral administration) of SYN-AR in one of three compositions (SYN-AR-A, SYN-AR-B or SYN-AR-C) per day for 3 days per week for the duration of 3 weeks
Control: three capsules of placebo (oral administration) per day for 3 days per week for the duration of 3 weeks

Randomisation: 1:1 block randomisation by sealed envelope. Placebo and the three verum prepatations are indistinguishable from each other.

Study Design:
1. Screening
2. Baseline exposure in an allergen exposure chamber
3. Post-intervention exposure in an allergen exposure chamber

Intervention Type
Supplement

Primary outcome(s)
Symptoms are measured using the Total Symptom Score (TSS, max. 24 Points) = Total Nose Symptom Score (TNSS, max. 12 Points) + Total Eye Symptom Score (TESS, max. 12 Points) at baseline and after the 3-week-intervention

Key secondary outcome(s))
Measured at baseline and at the post-intervention exposure:
1. Eye symptoms measured using the Max. Total Eye Symptom Score (TESS)
2. Nasal symptoms measured using the Max. Total Nasal Symptom Score (TNSS)
3. Bronchial symptoms measured using the Max. Total Bronchial Symptom Score (TBSS)

4. Other symptoms measured using the Total Other Symptom Score (TOSS)
5. Peak Nasal Inspiratory Flow (PNIF) measured before and after each exposure
6. Spirometry (FEV1, FEV1/FVC, MEF25-75) measured before and after each exposure
7. Use of emergency medications and/or emergency case management
8. Number of incidents and number of subjects with adverse events related to ingestion of the dietary supplement SYN-AR
9. Number of incidents and number of individuals with late reactions and/or adverse events related to exposure after each exposure
10. Post-treatment follow-up questionnaire at 4 weeks after post-intervention exposure

Completion date
16/12/2022

Eligibility

Key inclusion criteria
1. Persons of either sex between 18 and 65 years of age
2. Oral and written consent
3. Patients with clinically relevant sensitization to grass pollen and allergic symptoms for at least 2 years
4. Positive skin prick test (SPT) to grass pollen
5. Proven response to exposure to grass pollen in the allergen exposure chamber
6. Patients who agree to undergo all examinations and procedures mentioned in the study protocol
7. Patients who are fully conversant with the German language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
166

Key exclusion criteria
1. Persons under 18 years of age
2. Acute infections

3. Current cancer diagnosis/cancer within the last 5 years or autoimmune disease
4. Gastrointestinal disorders that may affect the absorption and processing of orally ingested substances, such as congenital gastrointestinal malformations or acute gastrointestinal infections
5. Severe forms of the following underlying chronic diseases: neurological diseases, metabolic diseases, severe asthma or respiratory obstruction, congenital anomalies of the heart, gastrointestinal system, or lungs
6. Patients with an FEV1 <60% (predicted value) prior to allergen exposure
7. Mental illnesses (e.g., depression) in the last 2 years
8. Eating disorders (e.g. bulimia, anorexia nervosa) in the last 2 years
9. Pregnant or breastfeeding female subjects
10. Alcohol or drug abuse
11. Clinically relevant hypersensitivity to any of the ingredients of SYN-AR
12. Participation in clinical trials in the last 3 months
13. Placement in an institution due to court or official orders
14. Contraindications to epinephrine and/or other emergency medications (especially cetirizine)
15. Hyposensitization within the last 5 years against grass pollen
16. Heavy smokers (according to WHO definition more than 20 cigarettes daily)
17. Use of certain medications before baseline exposure as well as during the study. These are:
17.1. Decongestant nasal drops (3 days)
17.2. Antihistamines (5 days)
17.3. Anti-allergic eye drops and nasal sprays (1 week)
17.4. Topical steroids (2 weeks)
17.5. Systemic corticosteroids (3 weeks)
17.6. Probiotics (4 weeks)
17.7. Antibiotics (4 weeks)

Date of first enrolment
04/07/2022

Date of final enrolment
14/10/2022

Locations

Countries of recruitment
Germany

Study participating centre
ECARF Institute GmbH
Robert-Koch-Platz 7
Berlin
Germany
10115

Sponsor information

Organisation
FUTRUE R&S 2 GmbH

Funder(s)

Funder type
Industry

Funder Name
FUTRUE R&S 2 GmbH

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes