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Evidence of the benefit of SYN-53 in the treatment of patients with allergic rhinoconjunctivitis due to grass pollen and associated symptoms

Submission date
01/02/2021

Recruitment status
No longer recruiting

Registration date
05/02/2021

Overall study status
Completed

Last Edited
05/02/2021

Condition category
Respiratory

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evidence of the benefit of SYN-53 in a double-blind, placebo-controlled monocentric study in the treatment of patients with allergic rhinoconjunctivitis due to grass pollen and associated symptoms

Acronym
SYN-53

Study objectives
The reduction of the total symptom score is significantly greater after consumption of SYN-53 than after consumption of placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/09/2020, Ethik-Kommission der Charite Berlin (Ethics commission of Charite Berlin, Charitèplatz 1, 10117 Berlin, Germany; +49 30 450 517 222; ethikkommission@charite.de), ref: EA1/216/20

Study design
Monocentric randomized double-blind placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
Treatment: 3 capsules (oral administration) of SYN-53 per day for 3 days after each exposure
Control: 3 capsules of placebo (oral administration) per day for 3 days after each exposure

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

Study Design:
1. Screening
2. Baseline exposure
3. Repeated biweekly exposure in an allergen exposure chamber (AEC)

Intervention Type
Supplement

Primary outcome measure
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 at repeated biweekly intervals (max. 3 exposures)

Secondary outcome measures
Measured at baseline and at repeated biweekly intervals (max. 3 exposures) unless otherwise noted:
1. Eye Symptoms using the Max. Total Eye Symptom Score (TESS)
2. Nasal Symptoms using the Max. Total Nasal Symptom Score (TNSS)
3. Bronchial Symptoms using the Max. Total Bronchial Symptom Score (TBSS)
4. Other Symptoms using the Total Other Symptom Score (TOSS)
5. Well-being using the Visual Analogue Scale (VAS)
6. Peak Nasal Inspiratory Flow (PNIF) before and after each exposure
7. Spirometrie (FEV1, FEV1/FVC, MEF25-75) before and after each exposure
8. Amount of nasal secretion by weighing handkerchiefs before and after each exposure
9. Use of emergency medications and/or emergency case management
10. Number of incidents and number of subjects with adverse events related to ingestion of the dietary supplement SYN-53 after each exposure
11. Number of incidents and number of individuals with late reactions and/or adverse events related to exposure after each exposure

Overall study start date
07/07/2020

Completion date
27/11/2020

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 AEC
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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Total final enrolment
90

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 <70% (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-53
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 V1 as well as during the study:
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
18/09/2020

Date of final enrolment
12/10/2020

Locations

Countries of recruitment
Germany

Study participating centre
ECARF Institute GmbH
Robert-Koch-Platz 7
Berlin
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Sponsor information

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
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Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
27/11/2021

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