Intranasal Ampligen in healthy volunteers.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21868

Source
NTR

Brief title
CHDR2049

Health condition

SARS-CoV-2, COVID-19, Corona

Sponsors and support

Primary sponsor: AIM ImmunoTech Inc.
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

• To assess the safety and tolerability of Ampligen administered intranasally in a dosing schedule for 13 days (7 doses) in healthy
subjects.
• To characterize the mucosal immune response following Ampligen administration over time.

Secondary outcome

N.A.

Study description

Background summary

Ampligen® is a well-defined selective Toll-like receptor 3 (TLR3) agonist inducing innate immune antiviral responses. Ampligen has been administered intravenously in approximately 100,000 doses in clinical trials and compassionate use programs. Besides, intranasal administration of Ampligen as a universal flu adjuvant was found to be well tolerated.

TLR3 is expressed at high level in human airway epithelial cells, including the nose and nasal pharynx. TLR3 serves as a pathogen recognition receptor to stimulate the innate immune response against many respiratory pathogens including coronaviruses. As a highly specific TLR3 agonist, Ampligen stimulates the production of type I interferons, which exert both antiviral and immunomodulatory activity.

The route of human infection of SARS-CoV-2 is believed to be primarily by entry into the nasal epithelium. By dosing Ampligen every other day intranasally, it is believed that SARS-CoV-2 can be inhibited at the point of entry, and thus will be much less likely to progress to a pulmonary infection, or moderate COVID-19 disease. These characteristics make Ampligen a potent candidate to be developed for an early treatment strategy and (post-exposure) prophylaxis against COVID-19. Because Ampligen does not act by binding to proteins or specific nucleic acid sequences of viruses it can also be developed for potential future outbreaks with pathogenic coronavisurses (CoVs), or even other respiratory viruses.

This phase I trial will assess the safety, tolerability and biological activity of repeated administration of Ampligen intranasally every other day for 13 days (7 doses) in healthy volunteers. This study is necessary for the further development of Ampligen as a potential treatment modality for COVID-19 and other pulmonary viral diseases.

Study objective

By dosing Ampligen every other day intranasally, it is believed that SARS-CoV-2 can be inhibited at the point of entry, and thus will be much less likely to progress to a pulmonary infection, or moderate COVID-19 disease.

Study design

Baseline till EOS

Intervention

Ampligen intranasally via a nasal sprayer
Placebo

Contacts

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Eligibility criteria

Inclusion criteria

1. Signed informed consent prior to any study-mandated procedure;
2. Male or female subjects, 18 to 70 years of age, inclusive at screening;
3. Body mass index (BMI) between 18 and 32 kg/m2, inclusive at screening, and with a minimum weight of 50 kg.
4. Participant must be healthy, in the investigator’s clinical judgment, as confirmed by medical history, physical examination, vital signs, ECG and laboratory assessments performed at screening;
5. Willing to comply with effective contraception during the study if subject is male or women of child bearing potential, up to 90 days after the last dose of study treatment.
6. Has the ability to communicate well with the investigator in the Dutch language and willing to comply with the study restrictions

Exclusion criteria

1. Evidence of any active or chronic disease or condition that could interfere with, or for which the treatment of might interfere with, the conduct of the study, or that would pose an unacceptable risk to the subject in the opinion of the investigator;
2. Clinically significant abnormalities, as judged by the investigator, in laboratory test results (including hepatic and renal panels, complete blood count, chemistry panel and urinalysis);
3. Positive hepatitis B surface antigen (HBsAg), hepatitis C antibody (HCV ab), or human

immunodeficiency virus antibody (HIV ab) at screening;
4. Respiratory tract infection (including flu and common cold symptoms) or any febrile illness (>38°celsius) in the period of 3 days before first treatment administration;
5. Presence of respiratory viral infection as determined by respiratory panel on nasal swab at baseline (including positive SARS-CoV-2 PCR test);
6. History of chronic respiratory diseases (e.g. chronic obstructive pulmonary disease, emphysema, chronic rhinitis or sinusitis, asthma or other reactive airway diseases) in adulthood. Childhood asthma and non-active allergic rhinitis (including hay fever) will be permitted at the discretion of the investigator;
7. History of frequent nose bleeds;
8. Significant anatomical nasal abnormalities or other nasal abnormalities that might impact the study executions (including, but not limited to, nasal septal defects, cleft palate, nasal polyps, previous nasal cautery or surgery that impacts study assessments);
9. Immunocompromised (known or expected immune deficiency, disease, or use of medication that may affect the immune system) or evidence of autoimmune disorder (deemed clinically relevant by the investigator);
10. Participation in an investigational drug or device study (last dosing of previous study was within 90 days or 5 half-lives prior to first dosing of this study);
11. History of abuse of addictive substances (alcohol, illegal substances) or current use of more than 21 units of alcohol per week, drug abuse, or regular user of sedatives, hypnotics, tranquillisers, or any other addictive agent;
12. Positive test for drugs of abuse at screening or pre-dose. Drugs test may be repeated;
13. A routine smoker of tobacco products, currently or in the past year. No (incidental) smoking will be allowed in the two weeks prior to first dosing;
14. Use of immunomodulatory drug; including systemic corticosteroids as well as nasal preparations within 30 days before first dosing;
15. Receipt of any vaccine within 1 week prior to IMP administration, or planning to get vaccinated during the study;
16. Therapy with interferons, interleukins, or other cytokines within 6 weeks of first dosing;
17. Known hypersensitivity to Ampligen or its excipients;
18. If a woman, pregnant, or breast feeding, or planning to become pregnant during the study;
19. Any known factor, condition, or disease that might interfere with treatment compliance, study conduct or interpretation of the results such as drug or alcohol dependence or psychiatric disease.
20. History of Bell’s Palsy or other forms of facial paralysis.
21. Loss or donation of blood over 500 mL within three months (males) or four months (females) prior to screening, or donation of plasma within 14 days of screening or intention to donate blood or blood products during
the study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-02-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Positive opinion

Date:	23-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50834
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9354
CCMO	NL76226.058.21
OMON	NL-OMON50834

Study results

Summary results
N.A.