Clinical study to evaluate safety, tolerability and effects on the immune system of a common cold vaccine in healthy adults

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19920

Bron
NTR

Verkorte titel
ITV1501

Aandoening

Prophylaxis against infection with Respiratory Syncytial Virus

Ondersteuning

Primaire sponsor: Intravacc, Bilthoven, the Netherlands
Overige ondersteuning: Ministry of public health and sports (VWS)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tolerability: Naso-oropharyngeal pain during and shortly after administration (VAS)
Safety:
- occurence in treatment-emergent (S)AEs
- occurrence and severity of solicited adverse events (local and systemic reactions)
- change in laboratory safety data, vital signs, body temperature

Toelichting onderzoek

Achtergrond van het onderzoek

Respiratory Syncytial Virus (RSV) is still the leading cause of hospitalization of children under 5 years of age. Currently, there is no effective treatment licensed for an ongoing RSV infection. Therefore, Intravacc develops a live-attenuated recombinant RSV vaccine. With reverse genetics, a virus was constructed from which the coding sequence for the G attachment protein was deleted from the RSV genome. This construct (RSVΔG) lacks the G protein resulting in severely impaired binding to host cells and therefore reducing infectivity. Due to this attenuation and limited spread, the vaccine is expected to induce an effective immune response, without inducing RSV symptoms.
This phase I trial evaluates the safety, tolerability, immunogenicity and shedding of the RSV vaccine in healthy adults.

Objectives

- To assess the safety and tolerability of live-attenuated RSV vaccine in healthy adults.

- To assess the immunogenicity of the live-attenuated RSV vaccine (systemic and mucosal immunity)

- To assess the viral load/shedding of the live-attenuated RSV vaccine

- To assess longevity of antibody response 6 months after immunization (if the vaccine was able to induce a significant increase in antibody titers on day 28)

Doel van het onderzoek

Respiratory Syncytial Virus (RSV) is still the leading cause of hospitalization of children under 5 years of age. Currently, there is no effective treatment licensed for an ongoing RSV infection. Therefore, Intravacc develops a live-attenuated recombinant RSV vaccine. With reverse genetics, a virus was constructed from which the coding sequence for the G

attachment protein was deleted from the RSV genome. This construct (RSVΔG) lacks the G protein resulting in severely impaired binding to host cells and therefore reducing infectivity. Due to this attenuation and limited spread, the vaccine is expected to induce an effective immune response, without inducing RSV symptoms.

Onderzoeksopzet

Day -3--1, day 0, 4, 7, 14 and 28 and follow-up at t= 6 months

Onderzoeksproduct en/of interventie

RSVdG Vaccine or placebo

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy male or female, 18-50 years of age, inclusive at screening;

2. Body mass index (BMI) > 18.0 and < 32.0 kg/m2;

3. Good health, based upon the results of medical history, physical examination, vital signs, ECG, and laboratory profiles of both blood and urine;

4. Pre-existing virus neutralization antibody titers (VNT) against RSV below 9.5 log2(titer) at screening;

5. Willing to comply with effective contraception during the study if subject is male or woman of child bearing potential, up to 90 days after the vaccine administration;

6. Signed informed consent prior to any study-mandated procedure;

7. The ability to communicate well with the Investigator in the Dutch language

8. Willing to comply with the study restrictions.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Immune-compromised (known or expected immune deficiency, disease, or use of medication that may affect the immune system);

2. Close contact with infants (<2 years of age) and immune-compromised individuals, during 14 days starting from day of vaccine administration;

3. Chronic airway diseases;

4. Airway infection in the period of 14 days before first vaccine administration;

5. Active hay fever or other allergies that involve the airways;

6. Any confirmed significant allergic reactions (urticaria or anaphylaxis) against any drug, or multiple drug allergies;

7. Any anatomic or neurologic abnormality impairing the gag reflex, or associated with an increased risk of aspiration, or any abnormality significantly altering the anatomy of the nose or nasopharynx;

8. History of frequent epistaxis (nose bleeds);

9. Evidence of any other 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.

10. Clinically significant abnormalities, as judged by the investigator, in laboratory test results

11. Positive Hepatitis B surface antigen, Hepatitis B antibody, Hepatitis C antibody, or human immunodeficiency virus antibody at screening;

12. If a woman, pregnant, or breast-feeding, or planning to become pregnant during the study or 90 days after vaccine administration;

13. Use of any medications (prescription or over-the-counter (OTC)), within 14 days of vaccine administration, or less than 5 half-lives (whichever is longer). Exceptions is are paracetamol (up to 4 g/day).. Other exceptions will only be made if the rationale is clearly documented and accepted by the investigator.

14. History of abuse of addictive substances (alcohol, illegal substances) or current use of more than 21 units alcohol per week, drug abuse, or regular user of sedatives, hypnotics, tranquillisers, or any other addictive agent;

15. Smoking for at leastin the 90 days preceding screening;

16. Positive test for drugs of abuse at screening or pre-dose;

17. Participation in an investigational drug or device study within 3 months prior to first dosing or more than 4 times a year;

18. Loss or donation of blood over 500 mL within three months (males) or four months (females) prior to screening or intention to donate blood or blood products during the study;

19. Any known factor, condition, or disease that might interfere with treatment compliance, study conduct or interpretation of the results.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	18-05-2018
Aantal proefpersonen:	48
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-04-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6984
NTR-old	NTR7173
Ander register	NL58147.000.17; LG 15-004; ITV1501; CHDR1542 : EudraCT 2016□-002437□-30

Resultaten