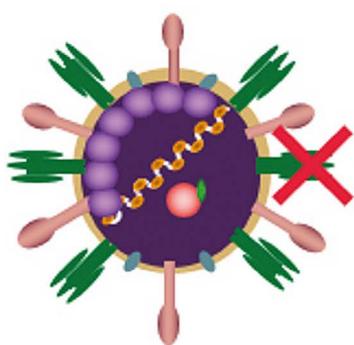
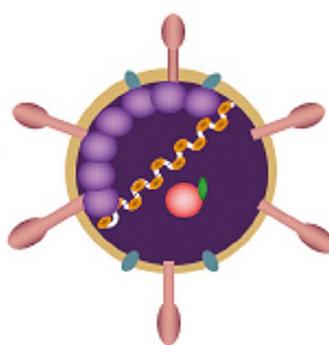


Pediatric live-attenuated RSV vaccine ITV-RSV- Δ G for mucosal immunization



wt-RSV



RSV Δ G



Respiratory syncytial virus (RSV) infection has an estimated global incidence of 33 million cases in children younger than 5 years, with 10% requiring hospital admission and up to 199,000 dying of the disease. It is also increasingly recognized as a cause of morbidity and mortality in those with underlying airway disease, people who are immunocompromised, and the frail elderly. A pediatric vaccine against RSV would not only prevent morbidity and mortality amongst young children, but would also reduce transmission to the elderly. Intravacc's live attenuated vaccine concept will enter in Phase I clinical studies in May 2018.

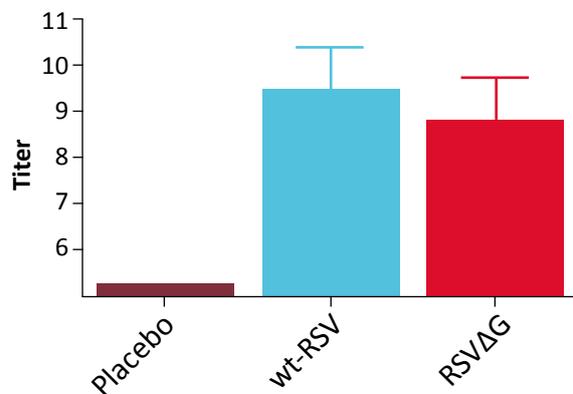
Vaccine concept

ITV-RSV- Δ G is a live-attenuated RSV vaccine that lacks the coding sequence for the G attachment protein. ITV-RSV- Δ G is severely impaired in binding to host cells and exhibits reduced infectivity. Due to this attenuation and limited spread, the vaccine can induce an effective immune response, without inducing RSV symptoms.

Benefits

- Patented live attenuated RSV concept
- Vero cell based production process at hand
- Mucosal delivery route
- First in human testing: May 2018
- Open for out-licensing/collaborative development
- Extensive track-record in technology transfer
- cGMP manufacturing capabilities

A Virus neutralizing titers in serum



B Protection upon challenge with wt-RSV

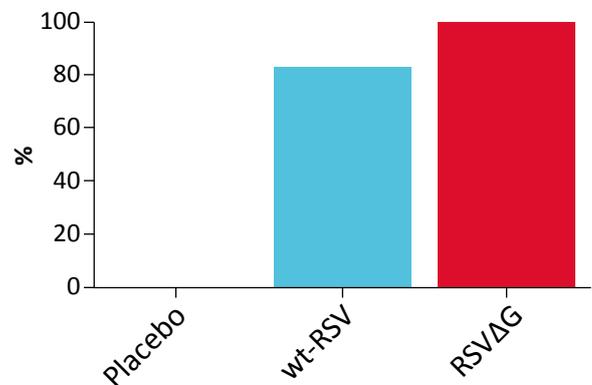


Figure 1. ITV-RSV-ΔG is highly immunogenic in cotton rats (A) and protects against challenge with wildtype RSV (B) after a single dose.

Target product profile

- Prevention of (severe) respiratory disease by RSV
- Infants 4-24 months old
- Live-attenuated vaccine
- One or two doses
- Intranasal delivery
- No enhanced disease

Preclinical safety and effectiveness

ITV-RSV-ΔG vaccine in cotton rat is:

- Highly attenuated
- Protects against challenge with wild type RSV
- Induced no enhanced disease in lungs after challenge infection with wild type RSV
- Provides long-lasting protection against RSV

A repeated-dose toxicity study with ITV-RSV-ΔG in Wistar rats revealed no safety concerns.

Production process

An animal-component free Vero Cell platform technology based production process has been developed up to 50L scale. A QC test panel has been developed for testing and release of clinical material for a Phase I clinical trial.

Phase I trial

In May 2018 a Phase I trial will commence studying the safety, immunogenicity and shedding of ITV-RSV-DG in healthy adults. Primary objective is safety, secondary objectives are viral replication and systemic and mucosal immunity.

Intravacc

Intravacc is a renowned, not-for-profit R&D organization. With our unique capabilities and infrastructure, we are able to optimize vaccines, vaccine processes and vaccine technologies. Our aim is to increase equality in access to vaccines throughout the world in order to contribute to public health. We achieve this by transferring our knowledge and technologies to public and private partners worldwide and through collaborative R&D. A team of 150 professionals is at your disposal at Utrecht Science Park Bilthoven in The Netherlands.

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