DIFFERENT DOSE LEVELS OF A RESPIRATORY SYNCYTIAL VIRUS MATERNAL VACCINE CANDIDATE (RSVPreF3) ADMINISTERED TO NON-PREGNANT WOMEN IN A RANDOMIZED CLINICAL TRIAL ARE IMMUNOGENIC AND WELL TOLERATED

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BACKGROUND AND AIM

Respiratory syncytial virus (RSV)-associated lower respiratory tract infections (LRTI) in infants could be prevented by maternal immunization[1]

RSV is a leading cause of LRTI in infants and children[1]

Immunization during pregnancy could protect young infants from RSV[1]

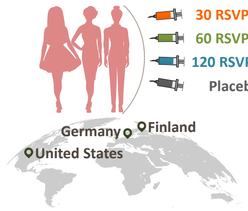
We evaluated the safety, reactogenicity and immunogenicity of the RSV maternal vaccine candidate (RSVPreF3) in non-pregnant women, at different dose levels

METHODS

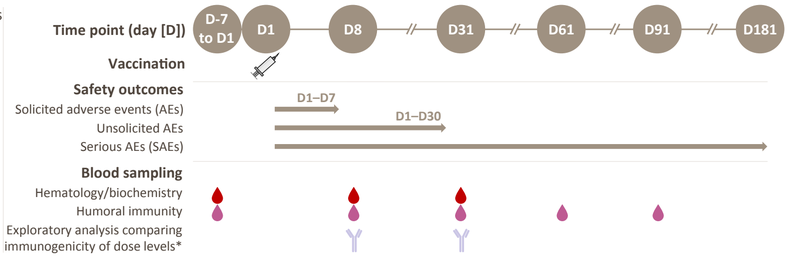
Phase I/II, observer-blind, randomized, multicenter study (NCT03674177)

Study population and groups

Healthy non-pregnant women aged 18–45 years randomized 1:1:1:1



Study procedures



*Only exploratory comparison on D31 are presented here; **30/60/120 RSVPreF3**, group of women who received RSV maternal vaccine at RSVPreF3 dose levels of 30, 60 or 120 µg.

CONCLUSIONS

- All RSVPreF3 vaccine dose levels were well tolerated and no safety concerns were identified
- Each of the 3 dose levels were immunogenic, with higher immune response induced by the 60 and 120 µg dose levels than the 30 µg one
- These data support further investigation of the 60 and 120 µg RSVPreF3 dose levels in pregnant women

- ✓ Different dose levels of maternal RSV vaccine candidate (RSVPreF3) were well tolerated and immunogenic in non-pregnant women
- ✓ The RSVPreF3 vaccine is a suitable candidate for further investigations in pregnant women

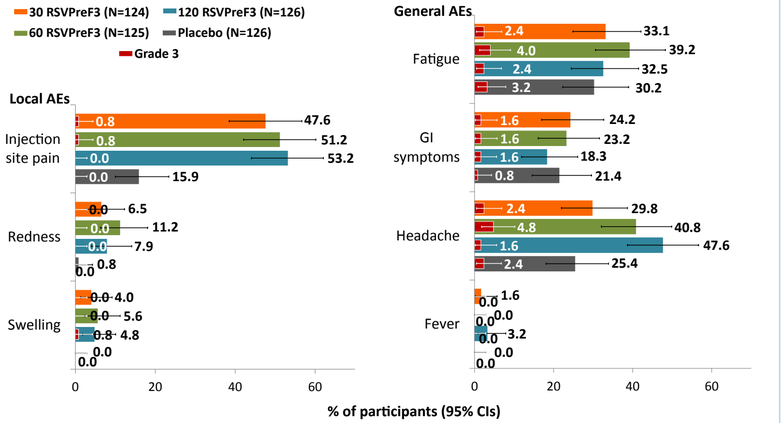
RESULTS

Study population characteristics

- 502 women were included in the exposed set (mean age: 32.1 years; 92.8% of white heritage)
- Demographic characteristics were well balanced across groups (data not shown)

Safety outcomes

The most common solicited AEs were injection site pain and headache; grade 3 solicited AEs were infrequently reported

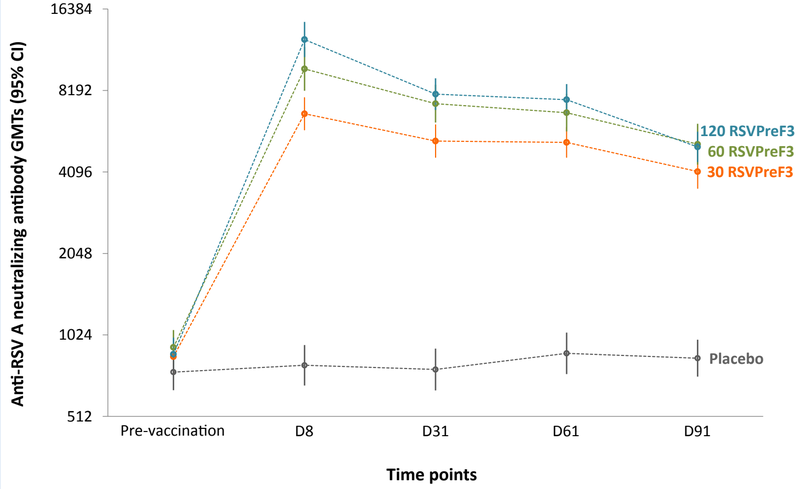


Exposed set (501 subjects were analyzed; 1 woman was lost to follow-up at D8 and the diary card was not returned). **N**, number of women with documented dose; **CI**, confidence interval; **GI**, gastrointestinal; **any fever**, ≥38.0 °C (regardless of the location of measurement but oral route was preferred); **grade 3**, significant **pain** at rest that prevents normal every day activities, diameter >100 mm (**redness and swelling**), preventing normal activities (**fatigue/GI symptoms/headache**), >39.0 °C (**fever**).

- 180 women experienced unsolicited AEs evenly distributed between groups; 19 reported grade 3 unsolicited AEs, among which 1 was vaccine-related (myalgia, in 60 RSVPreF3)
- 3 SAEs were reported (1 in 120 RSVPreF3; 2 in placebo); none were related to vaccination
- There were no occurrences of clinically significant changes in laboratory parameters

Immunogenicity outcomes

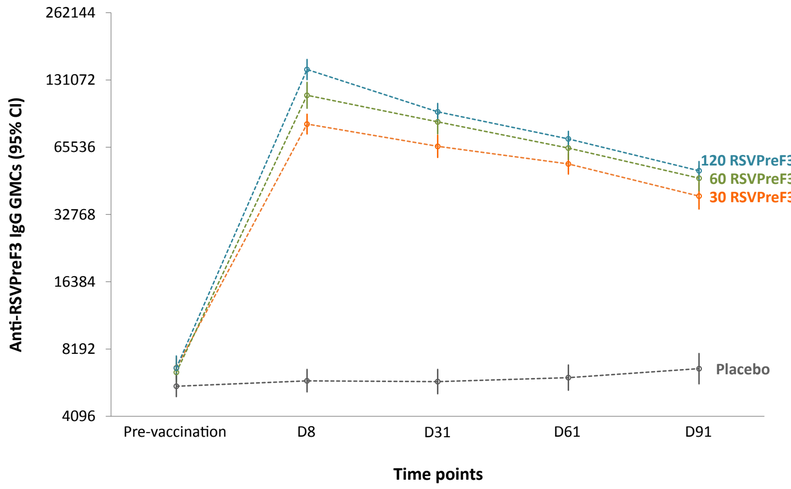
Geometric mean titers (GMTs) of anti-RSV A neutralizing antibody were boosted in all RSVPreF3 groups: ≥8-fold at D8 and ≥5-fold until D91 *vs* baseline



Per protocol set (defined by time point [at least 94% of women from the exposed set were part of the per protocol set at any of the time points]).

- The RSVPreF3 60 and 120 µg dose levels were significantly more immunogenic than the 30 µg one at D31

Geometric mean concentrations (GMCs) of anti-RSVPreF3 immunoglobulin G (IgG) antibody were boosted in all RSVPreF3 groups: ≥12-fold at D8 and ≥6-fold until D91 *vs* baseline



Per protocol set.

Reference: 1. Giersing et al. Vaccine 2019;37(50):7355–7362.

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