Title:

Author:

Affiliation

Abstract

Background

Methods

Study design

This prospective cohort study was conducted at My Duc Hospital and My Duc Phu Nhuan Hospital, Ho Chi Minh City, Vietnam, from August 2021 to December 2021. The study was approved by the institutional Medical Ethics Committee (15/2021/MD-HDDD) on November 18, 2021.

Study population

Between August 2021 and November 2021, pregnant women were offered vaccination against COVID-19 at My Duc Hospital, Ho Chi Minh City, Vietnam. The choice for Astra Zeneca or Pfizer-BioNTech vaccines depended on the availability of the vaccines at the time of vaccination. We prospectively investigated the side effects in the vaccinated pregnant women within 1 week after vaccination and followed their pregnancies till deliveries. 954 women who had received vaccination were included in this study and clustered into four groups of gestational age at the time they received vaccination based on the distribution (through interquartile rage) of gestational age at vaccination. Particularly, the gestational age at vaccination of four groups were <29.43, 29.43-32.71, 32.71-35.43, and ≥35.43 weeks, respectively.

Outcomes

The primary outcome of this study was to assess the impacts of the Covid-19 vaccination on maternal and gestational outcomes at different stages of gestational age.

Statistical analysis

Data were analyzed using descriptive statistics (mean and standard deviation for normally distributed variables, or median and interquartile range for skewed variables). Differences between groups were analyzed using Fisher’s exact test for categorical variables, Student's t-test for normally distributed continuous variables, and Mann-Whitney test for skewed variables. Post-hoc test were used to analyze the statistical differences between each group where the overall p-value was significant. All analyses were performed using the R statistical packages (R version 3.3.3). Statistical significance was defined as p<0.05.

Results

Discussion

Conclusion

Acknowledgement

References

Table 1. Baseline characteristics of pregnant, pregnancy, and neonatal outcomes in pregnant within each group of gestational age (weeks) at vaccination point of time of AstraZeneca received vaccination group

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Group 1  (19.71-29.43 weeks)  25.7±3.0 | Group 2  (29.57-32.57 weeks)  31.0±0.9 | Group 3  (32.71-35.43 weeks)  34.0±0.9 | Group 4  (35.5-39.71 weeks)  37.3±1.2 | p.overall |
|  | N=107 | N=109 | N=126 | N=93 |  |
| **Maternal baseline characteristics** |  |  |  |  |  |
| Maternal age – years | 32.1±4.2 | 31.6±4.0 | 31.9±4.5 | 32.5±4.8 | 0.465 |
| Previous pregnancies – n (%) |  |  |  |  | - |
| 0 | 75 (70.1) | 54 (49.5) | 52 (41.3) | 54 (58.1) |  |
| 1 | 19 (17.8) | 26 (23.9) | 34 (27.0) | 13 (14.0) |  |
| 2 | 9 (8.4) | 25 (22.9) | 31 (24.6) | 21 (22.6) |  |
| ≥3 | 4 (3.8) | 4 (3.7) | 9 (7.2) | 5 (5.4) |  |
| Type of pregnancy – n (%) |  |  |  |  | 0.007 |
| Assisted | 24 (22.4)abc | 12 (11.0) | 10 (7.9) | 10 (10.8) |  |
| Natural | 83 (77.6)abc | 97 (89.0) | 116 (92.1) | 83 (89.2) |  |
| Vaccination status – n (%) |  |  |  |  | <0.001 |
| Fully vaccinated | 31 (29.0)abc | 74 (67.9) | 100 (79.4)f | 56 (60.2) |  |
| Only 1 dose | 76 (71.0)abc | 35 (32.1) | 26 (20.6)f | 37 (39.8) |  |
| Gestational HBP before vaccination – n (%) | - | - | - | - | - |
| Gestational diabetes before vaccination – n (%) | 19 (17.8) | 17 (15.6) | 17 (13.5) | 5 (5.4) | 0.06 |
| Gestational oligohydramnios – n (%) | 5 (4.7) | 4 (3.7) | 3 (2.4) | 0 (0.0) | 0.17 |
| Gestational polyhydramnios – n (%) | 1 (0.9) | 3 (2.8) | 6 (4.8) | 4 (4.3) | 0.341 |
| **Gestational and Neonatal outcomes** |  |  |  |  |  |
| Maternal ICU events after vaccination – n (%) | - | - | - | - | - |
| Gestational HBP after vaccination – n (%) | 0 (0.0) | 0 (0.0) | 1 (0.8) | 0 (0.0) | 0.95 |
| Gestational diabetes after vaccination – n (%) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0 (0.0) | 0.71 |
| Gestational at birth – weeks | 37.8±2.6abc | 38.6±1.0 | 38.7±1.0 | 38.7±0.8 | <0.001 |
| Preterm delivery <28 weeks | 3 (2.8) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0.024 |
| Preterm delivery <34 weeks | 6 (5.6)ab | 0 (0.0) | 0 (0.0) | 0 (0.0) | <0.001 |
| Preterm delivery <37 weeks | 17 (15.9)abc | 5 (4.6) | 4 (3.2) | 2 (2.2) | <0.001 |
| Still birth – n (%) | 2 (1.9) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0.105 |
| Birthweights – grams | 3056.4±615.2 | 3137.7±365.3 | 3138.7±365.8 | 3186.8±294.8 | 0.184 |
| Low birthweight – n (%) | 8 (7.6)ac | 0 (0.0) | 3 (2.4) | 0 (0.0) | 0.001 |
| Heavy birthweight – n (%) | 2 (1.9) | 1 (0.9) | 1 (0.8) | 2 (2.2) | 0.736 |
| Birthweight percentile – [mean] percent | 50.8±28.5 | 47.0±29.0 | 46.8±28.8 | 47.6±25.3 | 0.698 |
| Birthweight percentile – [median] percent | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 0.666 |
| Lower than 10th percentile birthweight – n (%) | 6 (5.6) | 4 (3.7) | 7 (5.6) | 0 (0.0) | 0.072 |
| Neonatal ICU events – n (%) | 6 (5.6) | 3 (2.8) | 12 (9.5) | 3 (3.2) | 0.093 |
| Neonatal defects – n (%) | 2 (1.9) | 0 (0.0) | 2 (1.6) | 0 (0.0) | 0.315 |
| Maternal infected by Covid-19 – n (%) | 10 (9.3) | 12 (11.0) | 11 (8.7) | 5 (5.4) | 0.557 |

Values expressed as mean±SD, median [IQR], and n (%). Post hoc values expressed as letters, a: group 1 vs group 2 p<0.05, b: group 1 vs group 3 p<0.05, c: group 1 vs group 4 p<0.05, f: group 3 vs group 4 p<0.05

Table 2. Baseline characteristics of pregnant, pregnancy, and neonatal outcomes in pregnant within each group of gestational age (weeks) at vaccination point of time of PfizerBioNTech received vaccination group

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Group 1  (20-29.43 weeks)  27.1±2.0 | Group 2  (29.54-32.57 weeks)  31.1±1.0 | Group 3  (32.71-35.43 weeks)  34.0±0.8 | Group 4  (35.57-39.86 weeks)  37.3±1.0 | p.overall |
|  | N=128 | N=123 | N=115 | N=136 |  |
| **Maternal baseline characteristics** |  |  |  |  |  |
| Maternal ICU events after vaccination – n (%) | 31.4±4.3 | 30.9±4.4 | 30.4±4.4 | 30.4±4.7 | 0.244 |
| Previous pregnancies – n (%) |  |  |  |  | - |
| 0 | 57 (44.5) | 40 (32.5) | 36 (31.3) | 65 (47.8) |  |
| 1 | 37 (28.9) | 41 (33.3) | 40 (34.8) | 38 (27.9) |  |
| 2 | 27 (21.1) | 33 (26.8) | 33 (28.7) | 25 (18.4) |  |
| ≥3 | 7 (5.5) | 9 (7.3) | 6 (5.2) | 8 (5.8) |  |
| Type of pregnancy – n (%) |  |  |  |  | 0.001 |
| Assisted | 19 (14.8)ab | 3 (2.4) | 5 (4.3) | 10 (7.4) |  |
| Natural | 109 (85.2)ab | 120 (97.6) | 110 (95.7) | 126 (92.6) |  |
| Vaccination status – n (%) |  |  |  |  | <0.001 |
| Fully vaccinated | 81 (63.3)abc | 102 (82.9) | 100 (87.0) | 121 (89.0) |  |
| Only 1 dose | 47 (36.7)abc | 21 (17.1) | 15 (13.0) | 15 (11.0) |  |
| Gestational HBP before vaccination – n (%) | 1 (0.8) | 0 (0.0) | 1 (0.9) | 1 (0.7) | 0.898 |
| Gestational diabetes before vaccination – n (%) | 26 (20.3)c | 15 (12.2)d | 15 (13.0)f | 6 (4.4) | 0.001 |
| Gestational oligohydramnios – n (%) | 2 (1.6) | 4 (3.3) | 6 (5.2) | 3 (2.2) | 0.398 |
| Gestational polyhydramnios – n (%) | 5 (3.9) | 7 (5.7) | 7 (6.1) | 4 (2.9) | 0.591 |
| **Gestational and Neonatal outcomes** |  |  |  |  |  |
| Maternal ICU events after vaccination – n (%) | 1 (0.8) | 1 (0.8) | 0 (0.0) | 0 (0.0) | 0.729 |
| Gestational HBP after vaccination – n (%) | 0 (0.0) | 1 (0.8) | 3 (2.6) | 1 (0.7) | 0.209 |
| Gestational diabetes after vaccination – n (%) | 4 (3.1)ac | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0.027 |
| Gestational at birth – weeks | 38.2±1.7c | 38.5±1.5d | 38.6±1.2f | 38.9±0.7 | <0.001 |
| Preterm delivery <28 weeks | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | - |
| Preterm delivery <34 weeks | 5 (3.9) | 2 (1.6) | 1 (0.9) | 0 (0.0) | 0.056 |
| Preterm delivery <37 weeks | 14 (10.9)c | 12 (9.8)d | 7 (6.1)f | 1 (0.7) | 0.004 |
| Still birth – n (%) | 0 (0.0) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0.229 |
| Birthweights – grams | 3126.7±412.4 | 3130.2±415.5 | 3073.7±453.1 | 3183.3±355.2 | 0.213 |
| Low birthweight – n (%) | 8 (6.2) | 7 (5.7) | 10 (8.7) | 2 (1.5) | 0.079 |
| Heavy birthweight – n (%) | 2 (1.6) | 2 (1.6) | 3 (2.6) | 3 (2.2) | 0.923 |
| Birthweight percentile – [mean] percent | 51.0±28.7b | 48.3±27.6e | 41.0±28.8 | 46.6±28.1 | 0.048 |
| Birthweight percentile – [median] percent | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 25.0 [10.0;75.0] | 50.0 [25.0;75.0] | 0.04 |
| Lower than 10th percentile birthweight – n (%) | 4 (3.1)b | 4 (3.3) | 12 (10.4) | 7 (5.1) | 0.043 |
| Neonatal ICU events – n (%) | 6 (4.7) | 6 (4.9) | 7 (6.1) | 4 (2.9) | 0.683 |
| Neonatal defects – n (%) | 0 (0.0) | 0 (0.0) | 2 (1.7) | 2 (1.5) | 0.264 |
| Maternal infected by Covid-19 – n (%) | 14 (10.9) | 7 (5.7) | 7 (6.1) | 7 (5.1) | 0.236 |

Values expressed as mean±SD, median [IQR], and n (%). Post hoc values expressed as letters, a: group 1 vs group 2 p<0.05, b: group 1 vs group 3 p<0.05, c: group 1 vs group 4 p<0.05, d: group 2 vs group 3 p<0.05, e: group 2 vs group 4 p<0.05, f: group 3 vs group 4 p<0.05

Table S1. Baseline characteristics of pregnant within each group of gestational age (weeks) at vaccination point of time in non-infected women

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Group 1  (19.71-29.43 weeks)  26.5±2.6 | Group 2  (29.54-32.57 weeks)  31.0±0.9 | Group 3  (32.71-35.43 weeks)  34.0±0.8 | Group 4  (35.5-39.86 weeks)  37.3±1.1 | p.overall |
|  | N=211 | N=213 | N=223 | N=217 |  |
| **Maternal baseline characteristics** |  |  |  |  |  |
| Maternal age – years | 31.8±4.2 | 31.3±4.2 | 31.3±4.6 | 31.4±4.8 | 0.573 |
| Previous pregnancies – n (%) |  |  |  |  | - |
| 0 | 128 (60.7) | 92 (43.2) | 87 (39.0) | 118 (54.4) |  |
| 1 | 44 (20.9) | 59 (27.7) | 68 (30.5) | 47 (21.7) |  |
| 2 | 30 (14.2) | 51 (23.9) | 53 (23.8) | 40 (18.4) |  |
| ≥3 | 9 (4.2) | 11 (5.2) | 15 (6.7) | 12 (5.6) |  |
| Type of pregnancy – n (%) |  |  |  |  | <0.001 |
| Assisted | 41 (19.4)abc | 14 (6.6) | 15 (6.7) | 20 (9.2) |  |
| Natural | 170 (80.6)abc | 199 (93.4) | 208 (93.3) | 197 (90.8) |  |
| Vaccination status – n (%) |  |  |  |  | <0.001 |
| Fully vaccinated | 104 (49.3)abc | 159 (74.6) | 184 (82.5) | 165 (76.0) |  |
| Only 1 dose | 107 (50.7)abc | 54 (25.4) | 39 (17.5) | 52 (24.0) |  |
| Vaccince |  |  |  |  | 0.145 |
| AstraZeneca | 97 (46.0) | 97 (45.5) | 115 (51.6) | 88 (40.6) |  |
| Pfizer BioNTech | 114 (54.0) | 116 (54.5) | 108 (48.4) | 129 (59.4) |  |
| Gestational HBP before vaccination – n (%) | 1 (0.5) | 0 (0.0) | 1 (0.4) | 1 (0.5) | 0.904 |
| Gestational diabetes before vaccination – n (%) | 44 (20.9)bc | 29 (13.6)e | 28 (12.6)f | 10 (4.6) | <0.001 |
| Gestational oligohydramnios – n (%) | 7 (3.3) | 4 (1.9) | 7 (3.2) | 3 (1.4) | 0.485 |
| Gestational polyhydramnios – n (%) | 5 (2.4) | 8 (3.8) | 13 (5.8) | 7 (3.2) | 0.276 |
| **Gestational and Neonatal outcomes** |  |  |  |  |  |
| Maternal ICU events after vaccination – n (%) | - | - | - | - | - |
| Gestational HBP after vaccination – n (%) | 0 (0.0) | 1 (0.5) | 4 (1.8) | 1 (0.5) | 0.178 |
| Gestational diabetes after vaccination – n (%) | 2 (0.9) | 1 (0.5) | 1 (0.4) | 0 (0.0) | 0.477 |
| Gestational at birth – weeks | 38.0±2.3abc | 38.5±1.3e | 38.6±1.1f | 38.8±0.7 | <0.001 |
| Preterm delivery <28 weeks | 3 (1.4) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0.014 |
| Preterm delivery <34 weeks | 11 (5.2)abc | 2 (0.9) | 1 (0.4) | 0 (0.0) | <0.001 |
| Preterm delivery <37 weeks | 27 (12.8)bc | 17 (8.0)e | 11 (4.9)f | 2 (0.9) | <0.001 |
| Still birth – n (%) | 2 (0.9) | 0 (0.0) | 1 (0.4) | 0 (0.0) | 0.287 |
| Birthweights – grams | 3089.7±520.4 | 3130.6±391.4 | 3095.0±416.5 | 3180.9±324.2 | 0.089 |
| Low birthweight – n (%) | 14 (6.7)c | 7 (3.3) | 13 (5.8)f | 2 (0.9) | 0.012 |
| Heavy birthweight – n (%) | 3 (1.4) | 3 (1.4) | 4 (1.8) | 4 (1.8) | 0.95 |
| Birthweight percentile – [mean] percent | 51.4±28.4b | 48.0±28.0 | 43.3±28.9 | 46.7±27.0 | 0.026 |
| Birthweight percentile – [median] percent | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 0.022 |
| Lower than 10th percentile birthweight – n (%) | 9 (4.3) | 8 (3.8) | 19 (8.5)f | 7 (3.2) | 0.042 |
| Neonatal ICU events – n (%) | 11 (5.2) | 8 (3.8) | 19 (8.5)f | 5 (2.3) | 0.019 |
| Neonatal defects – n (%) | 2 (0.9) | 0 (0.0) | 3 (1.3) | 2 (0.9) | 0.508 |

Values expressed as mean±SD, median [IQR], and n (%). Post hoc values expressed as letters, a: group 1 vs group 2 p<0.05, b: group 1 vs group 3 p<0.05, c: group 1 vs group 4 p<0.05, f: group 3 vs group 4 p<0.05

Table S2. Baseline characteristics of pregnant, pregnancy, and neonatal outcomes in pregnant within each group of gestational age (weeks) at vaccination point of time of AstraZeneca received vaccination and non-infected group

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Group 1  (19.71-29.43 weeks)  25.6±3.0 | Group 2  (29.57-32.57 weeks)  31.0±0.9 | Group 3  (32.71-35.43 weeks)  34.0±0.9 | Group 4  (35.5-39.71 weeks)  37.3±1.2 | p.overall |
|  | N=97 | N=97 | N=115 | N=88 |  |
| **Maternal baseline characteristics** |  |  |  |  |  |
| Maternal age – years | 32.3±4.1 | 31.7±4.1 | 32.1±4.6 | 32.6±4.8 | 0.517 |
| Previous pregnancies – n (%) |  |  |  |  | - |
| 0 | 72 (74.2) | 52 (53.6) | 51 (44.3) | 54 (61.4) |  |
| 1 | 15 (15.5) | 21 (21.6) | 29 (25.2) | 11 (12.5) |  |
| 2 | 7 (7.2) | 22 (22.7) | 26 (22.6) | 18 (20.5) |  |
| ≥3 | 3 (3.1) | 2 (2.1) | 9 (7.8) | 5 (5.7) |  |
| Type of pregnancy – n (%) |  |  |  |  | 0.022 |
| Assisted | 22 (22.7)bc | 12 (12.4) | 10 (8.7) | 10 (11.4) |  |
| Natural | 75 (77.3)bc | 85 (87.6) | 105 (91.3) | 78 (88.6) |  |
| Vaccination status – n (%) |  |  |  |  | <0.001 |
| Fully vaccinated | 31 (32.0)abc | 64 (66.0)d | 91 (79.1)f | 51 (58.0) |  |
| Only 1 dose | 66 (68.0)abc | 33 (34.0)d | 24 (20.9)f | 37 (42.0) |  |
| Gestational HBP before vaccination – n (%) | - | - | - | - | - |
| Gestational diabetes before vaccination – n (%) | 18 (18.6) | 14 (14.4) | 14 (12.2) | 5 (5.7) | 0.068 |
| Gestational oligohydramnios – n (%) | 5 (5.2) | 2 (2.1) | 1 (0.9) | 0 (0.0) | 0.064 |
| Gestational polyhydramnios – n (%) | 0 (0.0) | 2 (2.1) | 6 (5.2) | 4 (4.5) | 0.082 |
| **Gestational and Neonatal outcomes** |  |  |  |  |  |
| Maternal ICU events after vaccination – n (%) | - | - | - | - | - |
| Gestational HBP after vaccination – n (%) | 0 (0.0) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0.95 |
| Gestational diabetes after vaccination – n (%) | 0 (0.0) | 1 (1.0) | 0 (0.0) | 0 (0.0) | 0.71 |
| Gestational at birth – weeks | 37.8±2.7abc | 38.5±1.0 | 38.7±1.0 | 38.7±0.7 | <0.001 |
| Preterm delivery <28 weeks | 3 (3.1) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0.039 |
| Preterm delivery <34 weeks | 6 (6.2)abc | 0 (0.0) | 0 (0.0) | 0 (0.0) | <0.001 |
| Preterm delivery <37 weeks | 15 (15.5)abc | 5 (5.2) | 4 (3.5) | 1 (1.1) | <0.001 |
| Still birth – n (%) | 2 (2.1) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0.167 |
| Birthweights – grams | 3053.1±620.2 | 3148.4±368.0 | 3120.7±370.9 | 3186.6±277.9 | 0.186 |
| Low birthweight – n (%) | 7 (7.4)ac | 0 (0.0) | 3 (2.6) | 0 (0.0) | 0.002 |
| Heavy birthweight – n (%) | 1 (1.1) | 1 (1.0) | 1 (0.9) | 1 (1.1) | 0.95 |
| Birthweight percentile – [mean] percent | 52.2±28.2 | 48.6±28.7 | 45.2±28.7 | 47.8±25.1 | 0.351 |
| Birthweight percentile – [median] percent | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 0.333 |
| Lower than 10th percentile birthweight – n (%) | 5 (5.2) | 4 (4.1) | 7 (6.1) | 0 (0.0) | 0.084 |
| Neonatal ICU events – n (%) | 6 (6.2) | 2 (2.1)d | 12 (10.4)f | 2 (2.3) | 0.031 |
| Neonatal defects – n (%) | 2 (2.1) | 0 (0.0) | 2 (1.7) | 0 (0.0) | 0.345 |

Values expressed as mean±SD, median [IQR], and n (%). Post hoc values expressed as letters, a: group 1 vs group 2 p<0.05, b: group 1 vs group 3 p<0.05, c: group 1 vs group 4 p<0.05, d: group 2 vs group 3 p<0.05, f: group 3 vs group 4 p<0.05

Table S3. Baseline characteristics of pregnant, pregnancy, and neonatal outcomes in pregnant within each group of gestational age (weeks) at vaccination point of time of PfizerBioNTech received vaccination and non-infected group

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Group 1  (20-29.43 weeks)  27.1±2.0 | Group 2  (29.54-32.57 weeks)  31.1±1.0 | Group 3  (32.71-35.43 weeks)  34.0±0.8 | Group 4  (35.57-39.86 weeks)  37.2±1.0 | p.overall |
|  | N=114 | N=116 | N=108 | N=129 |  |
| **Maternal baseline characteristics** |  |  |  |  |  |
| Maternal ICU events after vaccination – n (%) | 31.5±4.2 | 31.1±4.3 | 30.4±4.4 | 30.5±4.7 | 0.262 |
| Previous pregnancies – n (%) |  |  |  |  | - |
| 0 | 56 (49.1) | 40 (34.5) | 36 (33.3) | 64 (49.6) |  |
| 1 | 29 (25.4) | 38 (32.8) | 39 (36.1) | 36 (27.9) |  |
| 2 | 23 (20.2) | 29 (25.0) | 27 (25.0) | 22 (17.1) |  |
| ≥3 | 6 (5.3) | 9 (7.8) | 6 (5.5) | 7 (5.5) |  |
| Type of pregnancy – n (%) |  |  |  |  | <0.001 |
| Assisted | 19 (16.7) | 2 (1.7) | 5 (4.6) | 10 (7.8) |  |
| Natural | 95 (83.3) | 114 (98.3) | 103 (95.4) | 119 (92.2) |  |
| Vaccination status – n (%) |  |  |  |  | <0.001 |
| Fully vaccinated | 73 (64.0) | 95 (81.9) | 93 (86.1) | 114 (88.4) |  |
| Only 1 dose | 41 (36.0) | 21 (18.1) | 15 (13.9) | 15 (11.6) |  |
| Gestational HBP before vaccination – n (%) | 1 (0.9) | 0 (0.0) | 1 (0.9) | 1 (0.8) | 0.803 |
| Gestational diabetes before vaccination – n (%) | 26 (22.8) | 15 (12.9) | 14 (13.0) | 5 (3.9) | <0.001 |
| Gestational oligohydramnios – n (%) | 2 (1.8) | 2 (1.7) | 6 (5.6) | 3 (2.3) | 0.324 |
| Gestational polyhydramnios – n (%) | 5 (4.4) | 6 (5.2) | 7 (6.5) | 3 (2.3) | 0.446 |
| **Gestational and Neonatal outcomes** |  |  |  |  |  |
| Maternal ICU events after vaccination – n (%) | 1 (0.9) | 1 (0.9) | 0 (0.0) | 0 (0.0) | 0.599 |
| Gestational HBP after vaccination – n (%) | 0 (0.0) | 1 (0.9) | 3 (2.8) | 1 (0.8) | 0.243 |
| Gestational diabetes after vaccination – n (%) | 2 (1.8) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0.182 |
| Gestational at birth – weeks | 38.2±1.7c | 38.5±1.5e | 38.6±1.2f | 38.9±0.7 | <0.001 |
| Preterm delivery <28 weeks | - | - | - | - | - |
| Preterm delivery <34 weeks | 5 (4.4)c | 2 (1.7) | 1 (0.9) | 0 (0.0) | 0.047 |
| Preterm delivery <37 weeks | 12 (10.5)c | 12 (10.3)e | 7 (6.5)f | 1 (0.8) | 0.007 |
| Still birth – n (%) | 0 (0.0) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0.231 |
| Birthweights – grams | 3120.8±417.6 | 3115.7±410.9 | 3067.7±460.3 | 3176.9±353.2 | 0.238 |
| Low birthweight – n (%) | 7 (6.1) | 7 (6.0) | 10 (9.3) | 2 (1.6) | 0.076 |
| Heavy birthweight – n (%) | 2 (1.8) | 2 (1.7) | 3 (2.8) | 3 (2.3) | 0.947 |
| Birthweight percentile – [mean] percent | 50.7±28.8 | 47.6±27.6 | 41.1±29.1 | 46.0±28.3 | 0.089 |
| Birthweight percentile – [median] percent | 50.0 [25.0;75.0] | 50.0 [25.0;75.0] | 37.5 [10.0;75.0] | 50.0 [25.0;75.0] | 0.073 |
| Lower than 10th percentile birthweight – n (%) | 4 (3.5)b | 4 (3.4)d | 12 (11.1) | 7 (5.4) | 0.048 |
| Neonatal ICU events – n (%) | 5 (4.4) | 6 (5.2) | 7 (6.5) | 3 (2.3) | 0.439 |
| Neonatal defects – n (%) | 0 (0.0) | 0 (0.0) | 1 (0.9) | 2 (1.6) | 0.512 |

Values expressed as mean±SD, median [IQR], and n (%). Post hoc values expressed as letters, b: group 1 vs group 3 p<0.05, c: group 1 vs group 4 p<0.05, d: group 2 vs group 3 p<0.05, e: group 2 vs group 4 p<0.05, f: group 3 vs group 4 p<0.05

Table 3. Regression analysis for the joint effects of maternal and gestational characteristics on the preterm delivery before 28 weeks of gestational age

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Normal | Preterm birth 28 weeks | OR [95% CI]; p-value | OR [95% CI]; p-value\* |
|  | N=951 | N=3 |  |  |
| Maternal age | 31.3±4.5 | 38.0±5.6 | 1.4 [1.1;1.8]; 0.02 | 1.7 [0.97;2.98]; 0.06 |
| ART | 92 (9.7) | 2 (66.7) | 18.7 [1.7;207.9]; 0.02 | 1.3 [0.07;24.6]; 0.7 |
| Gestational age at vaccination | 32.2±4.2 | 21.8±2.4 | 0.5 [0.2;0.9]; 0.02 | 0.4 [0.1;1.02]; 0.054 |
| Vaccination type |  |  |  |  |
| AZ | 438 (46.1) | 3 (100.0) | - | - |
| Pfizer | 513 (53.9) | 0 (0.0) | - | - |

Values expressed as mean±SD and n (%). \* denoted for the adjusted p-value carried out by multiple regression analysis

Table 4. Regression analysis for the joint effects of maternal and gestational characteristics on the preterm delivery before 34 weeks of gestational age

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Normal | Preterm birth 34 weeks | OR [95% CI]; p-value | OR [95% CI]; p-value\* |
|  | N=940 | N=14 |  |  |
| Maternal age | 31.4±4.4 | 31.6±6.4 | 1.01 [0.9;1.14]; 0.86 | - |
| ART | 91 (9.7) | 3 (21.4) | 2.5 [0.7;9.3]; 0.15 | 0.9 [0.2;3.6]; 0.87 |
| Gestational age at vaccination | 32.3±4.2 | 26.0±4.2 | 0.7 [0.65;0.83]; <0.001 | 0.7 [0.64;0.83]; <0.001 |
| Vaccination type |  |  |  |  |
| Pfizer | 505 (53.7) | 8 (57.1) | Reference | - |
| AZ | 435 (46.3) | 6 (42.9) | 0.87 [0.3;2.5]; 0.8 | - |

Values expressed as mean±SD and n (%). \* denoted for the adjusted p-value carried out by multiple regression analysis

Table 5. Regression analysis for the joint effects of maternal and gestational characteristics on the preterm delivery before 37 weeks of gestational age

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Normal | Preterm birth 37 weeks | OR [95% CI]; p-value | OR [95% CI]; p-value\* |
|  | N=892 | N=62 |  |  |
| Maternal age | 31.4±4.4 | 30.9±4.9 | 0.97 [0.9;1.03]; 0.37 | - |
| ART | 87 (9.8) | 7 (11.3) | 1.3 [0.7;2.2]; 0.37 | - |
| Gestational age at vaccination | 32.4±4.2 | 29.6±3.7 | 0.87 [0.82;0.92]; <0.001 | 0.86 [0.8;0.9]; <0.001 |
| Vaccination type |  |  |  |  |
| Pfizer | 579 (53.7) | 34 (54.8) | Reference | - |
| AZ | 413 (46.3) | 28 (45.2) | 0.87 [0.3;2.5]; 0.8 | - |
| Gestational diabetes before vaccinated | 116 (13.0) | 4 (6.5) | 0.5 [0.2;1.3]; 0.14 | 0.35 [0.12;0.99]; 0.048 |

Values expressed as mean±SD and n (%). \* denoted for the adjusted p-value carried out by multiple regression analysis

Table S5. Regression analysis for the joint effects of maternal and gestational characteristics on the preterm delivery before 34 weeks of gestational age

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Normal | Preterm birth 34 weeks | OR [95% CI]; p-value | OR [95% CI]; p-value\* |
|  | N=940 | N=11 |  |  |
| Maternal age | 31.4±4.4 | 31.6±6.4 | 0.922 [0.801;1.06]; 0.253 | - |
| ART | 91 (9.7) | 1 (9.1) | 0.933 [0.118;7.371]; 0.948 | - |
| Gestational age at vaccination | 32.3±4.2 | 27.1±3.8 | 0.78 [0.68;0.89]; <0.001 | 0.7 [0.64;0.83]; <0.001 |
| Vaccination type |  |  |  |  |
| Pfizer | 505 (53.7) | 8 (72.7) | Reference | - |
| AZ | 435 (46.3) | 3 (27.3) | 0.44 [0.12;1.65]; 0.22 | 0.3 [0.07;1.2]; 0.09 |

Values expressed as mean±SD and n (%). \* denoted for the adjusted p-value carried out by multiple regression analysis

Table S6. Regression analysis for the joint effects of maternal and gestational characteristics on the preterm delivery before 37 weeks of gestational age

|  |  |  |  |
| --- | --- | --- | --- |
|  | Normal | Preterm birth 37 weeks | OR [95% CI]; p-value |
|  | N=892 | N=48 |  |
| Maternal age | 31.4±4.4 | 30.7±4.5 | 0.963 [0.9;1.029]; 0.265 |
| ART | 87 (9.8) | 4 (8.3) | 0.841 [0.295;2.397]; 0.746 |
| Gestational age at vaccination | 32.4±4.2 | 30.7±2.8 | 0.915 [0.857;0.977]; 0.008 |
| Vaccination type |  |  |  |
| Pfizer | 579 (53.7) | 26 (54.2) | Reference |
| AZ | 413 (46.3) | 22 (45.8) | 0.981 [0.548;1.758]; 0.95 |
| Gestational diabetes before vaccinated | 116 (13.0) | 4 (8.3) | 0.608 [0.215;1.724]; 0.35 |

Values expressed as mean±SD and n (%)