Rapid response to

**Covid-19 vaccines and treatments: we must have raw data, now**

**Data should be fully and immediately available for public scrutiny**

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Dear Sir,

Vaccination has been the most effective strategy against COVID-19 disease caused by SARS-CoV-2. In view of the disruptive nature of the pandemic, these vaccines have understandably been approved after shortened assessment trajectories. There is little comparative evidence assessing the side effects of COVID-19 vaccines in pregnancy. We compared pregnancy and neonatal outcomes in Vietnamese women vaccinated against COVID-19 with Astra Zeneca and Pfizer.

**Methods**

Between August 2021 and November 2021, 954 pregnant women were offered randomization against COVID-19 at around 31-32 weeks of pregnancy at My Duc Hospital, Ho Chi Minh City, Vietnam. Out of them, 441 pregnant women got vaccinated with Astra Zeneca and 513 with Pfizer. The choice for Astra Zeneca or Pfizer vaccines depends on the availability of the vaccines at the time.

**Results**

**Table 1**. Baseline characteristics of pregnant women vaccinated against COVID-19

|  |  |  |  |
| --- | --- | --- | --- |
| **Baseline demographics** | **Astra Zeneca**  **N=441** | **Pfizer**  **N=513** | **p-value** |
| Maternal age – years | 31.99±4.37 | 30.83±4.47 | <0.001 |
| Previous pregnancies – n (%) |  |  | <0.001 |
| 0 | 240 (54.42%) | 206 (40.16%) |  |
| 1 | 92 (20.86%) | 158 (30.80%) |  |
| 2 | 87 (19.73%) | 119 (23.20%) |  |
| ≥ 3 | 22 (4.98%) | 30 (5.84%) |  |
| Type of pregnancy – n (%) |  |  | 0.009 |
| Natural | 385 (87.30%) | 475 (92.59%) |  |
| IVF | 56 (12.70%) | 38 (7.41%) |  |
| Number of vaccination dose – n (%) |  |  | <0.001 |
| Only 1 dose | 176 (39.9%) | 99 (19.3%) |  |
| Fully vaccinated | 265 (60.1%) | 414 (80.7%) |  |
| Gestational age at vaccination – weeks | 31.91±4.47 | 32.42±4.02 | 0.067 |
| High blood pressure before vaccination | 0 (0.00%) | 3 (0.58%) | . |
| Diabetes before vaccination | 58 (13.15%) | 62 (12.09%) | 0.691 |

**Table 2.** Side effects in vaccinated pregnant women

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Side effects – n (%)** | **Astra Zeneca** | | **Pfizer** | | **P1** | **P2** |
| **First dose**  **(N=441)** | **Second dose**  **(N=265)** | **First dose**  **(N=513)** | **Second dose**  **(N=414)** |
| Pain and wat injection site | 347 (78.7%) | 37 (14.0%) | 411 (80.1%) | 167 (40.4%) | 0.642 | <0.001 |
| Swelling at injection site | 43 (9.8%) | 6 (2.3%) | 45 (8.8%) | 26 (6.3%) | 0.683 | 0.026 |
| Redness at injection site | 11 (2.5%) | 1 (0.4%) | 8 (1.6%) | 11 (2.7%) | 0.425 | 0.034 |
| Itching at injection site | 70 (15.9%) | 5 (1.9%) | 64 (12.5%) | 9 (2.2%) | 0.158 | 1 |
| Self reported fatigue | 261 (59.2%) | 15 (5.7%) | 60 (11.7%) | 64 (15.5%) | <0.001 | <0.001 |
| Sore throat | 10 (2.3%) | 0 (0.0%) | 1 (0.2%) | 0 (0.0%) | 0.007 | . |
| Runny nose | 5 (1.1%) | 0 (0.0%) | 2 (0.4%) | 0 (0.0%) | 0.259 | . |
| Coughing | 6 (1.4%) | 0 (0.0%) | 0 (0.0%) | 2 (0.5%) | 0.01 | 0.524 |
| Headache | 183 (41.5%) | 7 (2.7%) | 43 (8.4%) | 37 (9.0%) | <0.001 | 0.002 |
| Muscle pain | 187 (42.4%) | 10 (3.8%) | 49 (9.6%) | 38 (9.2%) | <0.001 | 0.012 |
| Chilling | 159 (36.1%) | 5 (1.9%) | 14 (2.7%) | 16 (3.9%) | <0.001 | 0.222 |
| Over 38oC fever | 113 (25.6%) | 13 (4.9%) | 1 (0.2%) | 49 (11.9%) | <0.001 | 0.004 |
| Nausea | 34 (7.7%) | 0 (0.0%) | 5 (1.0%) | 5 (1.2%) | <0.001 | 0.162 |
| Joint pain | 78 (17.7%) | 19 (7.2%) | 8 (1.6%) | 14 (3.4%) | <0.001 | 0.039 |
| Stomachache | 7 (1.6%) | 2 (0.8%) | 1 (0.2%) | 0 (0.0%) | 0.028 | 0.152 |
| Diarrhea | 16 (3.6%) | 0 (0.0%) | 2 (0.4%) | 2 (0.5%) | 0.001 | 0.524 |
| Rash skin | 4 (0.9%) | 1 (0.4%) | 1 (0.2%) | 0 (0.0%) | 0.188 | 0.39 |
| Vaginal haemorrhage | 4 (0.9%) | 0 (0.0%) | 1 (0.2%) | 0 (0.0%) | 0.188 | . |
| Others | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0.527 | . |
| Thrombocytopenia | 6 (1.4%) | 1 (0.4%) | 4 (0.8%) | 4 (1.0%) | . | 0.653 |
| Myocarditis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | . | . |
| Anaphylactic shock | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | . | . |

**Table 3**. Pregnancy and neonatal outcomes in pregnant women vaccinated against COVID-19

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Astra Zeneca**  **(N=441)** | **Pfizer**  **(N=513)** | **RR**  **(95% CI)** | **Between group difference**  **(95% CI)** | **p** |
| **Pregnancy outcomes** | | | | | |
| High blood pressure after vaccination | 1 (0.23%) | 5 (0.97%) | 4.3 (0.5, 36.65) | 0.75 (-0.42, 1.92) | 0.225 |
| Diabetes after vaccination | 1 (0.23%) | 5 (0.97%) | 4.3 (0.5, 36.65) | 0.75 (-0.42, 1.92) | 0.225 |
| Gestational age at birth – weeks | 38.44±1.60 | 38.57±1.34 | - | 0.1 (-0.1, 0.3) | 0.176 |
| Preterm delivery – n (%) |  |  |  |  |  |
| < 28 weeks | 3 (0.68%) | 0 (0%) | - | - | - |
| < 34 weeks | 6 (1.36%) | 8 (1.56%) | 1.15 (0.4, 3.28) | 0.2 (-1.52, 1.92) | 0.95 |
| < 37 weeks | 28 (6.35%) | 34 (6.63%) | 1.04 (0.64, 1.69) | 0.28 (-3.07, 3.62) | 0.9 |
| Oligohydramnios | 12 (2.73%) | 15 (2.92%) | 1.07 (0.51, 2.26) | 0.19 (-2.11, 2.49) | 0.95 |
| Polyhydramnios | 14 (3.17%) | 23 (4.48%) | 1.41 (0.74, 2.71) | 1.31 (-1.33, 3.95) | 0.381 |
| Being monitored at ICU | 0 (0) | 2 (0.39) | - | - | - |
| Stillbirth | 2 (0.45) | 1 (0.19) | -0.26 (-1.2, 0.69) | 0.43 (0.04, 4.72) | 0.6 |
| Maternal death | 0 (0.00%) | 0 (0.00%) | - | - | . |
| **Neonatal outcomes** | | | | | |
| Birth weight - grams | 3148.25±376.76 | 3132.10±403.51 | - | -16.1 (-65.9, 33.6) | 0.524 |
| Low birth weight (under 2500g) | 11 (2.51%) | 27 (5.26%) | 2.1 (1.05, 4.18) | 2.75 (0.12, 5.39) | 0.046 |
| Heavy birth weight (over 4000g) | 6 (1.37%) | 10 (1.95%) | 1.42 (0.52, 3.88) | 0.58 (-1.25, 2.41) | 0.66 |
| Birthweight percentile | 50.00 [25.00; 75.00] | 50.00 [25.00; 75.00] | - | - | 0.445 |
| BirtHweight < 10th percentile | 65 (14.74%) | 85 (16.57%) | 1.12 (0.84, 1.51) | 1.83 (-3, 6.66) | 0.493 |
| NICU | 24 (5.45%) | 23 (4.49%) | 0.82 (0.47, 1.44) | -0.96 (-3.95, 2.03) | 0.594 |
| Birth defects | 4 (0.91%) | 4 (0.78%) | 0.86 (0.22, 3.42) | -0.13 (-1.42, 1.17) | 0.95 |

**Table 4.** Growth of babies against gestational age

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **<34** | | **34-<37** | | **37-<38** | | **38-<39** | | **39-<40** | | **40-<41** | | **41** | |
|  | AZ  (N = 6) | Pf  (N = 8) | AZ  (N = 22) | Pf  (N = 26) | AZ  (N = 53) | Pf  (N = 55) | AZ  (N = 175) | Pf  (N = 164) | AZ  (N = 145) | Pf  (N = 203) | AZ  (N = 39) | Pf  (N = 55) | AZ  (N = 1) | Pf  (N = 1) |
| **Still birth** | 2 (33.3) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| **<p10** | 1 (16.7) | 1 (12.5) | 2 (9.1) | 6 (23.1) | 3 (5.7) | 2 (3.6) | 7 (4) | 5 (3) | 2 (1.4) | 12 (5.9) | 1 (2.6) | 0 (0) | 0 (0) | 0 (0) |
| **p10-p25** | 0 (0) | 0 (0) | 2 (9.1) | 2 (7.7) | 4 (7.5) | 7 (12.7) | 20 (11.4) | 16 (9.8) | 14 (9.7) | 26 (12.8) | 7 (17.9) | 8 (14.5) | 0 (0) | 0 (0) |
| **p25-p50** | 2 (33.3) | 2 (25) | 6 (27.3) | 10 (38.5) | 12 (22.6) | 13 (23.6) | 39 (22.3) | 38 (23.2) | 45 (31) | 53 (26.1) | 10 (25.6) | 11 (20) | 0 (0) | 1 (100) |
| **p50-75** | 1 (16.7) | 1 (12.5) | 5 (22.7) | 3 (11.5) | 13 (24.5) | 21 (38.2) | 38 (21.7) | 41 (25) | 43 (29.7) | 49 (24.1) | 14 (35.9) | 23 (41.8) | 1 (100) | 0 (0) |
| **p75-p90** | 0 (0) | 1 (12.5) | 2 (9.1) | 3 (11.5) | 8 (15.1) | 4 (7.3) | 50 (28.6) | 41 (25) | 27 (18.6) | 41 (20.2) | 6 (15.4) | 9 (16.4) | 0 (0) | 0 (0) |
| **>p90** | 0 (0) | 3 (37.5) | 5 (22.7) | 2 (7.7) | 13 (24.5) | 8 (14.5) | 21 (12) | 23 (14) | 14 (9.7) | 22 (10.8) | 1 (2.6) | 4 (7.3) | 0 (0) | 0 (0) |

**Conclusion**

COVID-19 vaccines are generally safe and well-tolerated among pregnant women. Pfizer vaccines in pregnant women is associated with higher rate of low birthweight as compared with Astra Zeneca.

**Competing interests:** No competing interests.

Sincerely,

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