Therapeutic Effect of Xagrotin Against SARS-CoV-2: In silico, In vitro, In Vivo, and Clinical Trial Study

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# Clinical trial results

Demographic and clinical characteristics of COVID-19 patients registered in the current clinical trial were presented in table 1.

Table 1. Patient characteristics

|  |  |  |  |
| --- | --- | --- | --- |
| **Characteristic** | **Study group (n=361)** | **Control Group (n=178)** | **P value** |
| **Sex-no (%)** |  |  |  |
| Male | 204 (56.5) | 87 (49) | 0.240 |
| Female | 157 (43.5) | 91 (51) |
| **Age (Mean ± SD)** | 43.9 ± 17.2 | 44.3 ±17.2 | 0.811 |
| **Duration of symptoms before enrolment**  **(days, Mean ± SD)** | 7.2 ± 4.4 | 3.5 ± 3 | <0.001 |
| **Smoker-no (%)** | 24 (6) | 21 (11.9) | 0.089 |
| **Moderate to severe** **Underlying Disease-no (%) \*** |  |  |  |
| - Pulmonary diseases | 3 (0.8) | 4 (2.2) | 0.091 |
| - Cardiovascular diseases | 26 (7.2) | 27 (15.2) |
| - Diabetes Mellitus | 9 (2.5) | 16 (9) |
| - Cancer | 3 (0.8) | 0 (0) |
| \* Number and percentage of patients who have at least one of the chronic diseases. | | | |

The delay in starting Xagrotin, in comparison to standard treatments (control group), is mainly because of the period patients have tried standard of care before they decide to shift to the Xagrotin or add Xagrotin to their standard treatments so we adjusted our next analysis based this delay time.

The mortality rate on day 30 indicated over 9-fold less mortality rate in the study group compared to the control group (0.55% in the study group vs 5.6% in the control group, respectively (p<0.001). Xagrotin shortened the duration of the disease by 2-fold, the rate of hospitalization by 10-fold, and the duration of hospitalization by 9-fold (Table 2).

Table 2: Odd ratio for the associated variables.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Results** | **Treatment group (n=361)** | **Control Group (n=178)** | **p-value** | **OR** | **95% CI** | |
| **Lower limit** | **Upper limit** |
| **The mortality rate on day 30**  **no (%)** | 2 (0.55) | 10 (5.6) | <0.001 | 0.093 | 0.020 | 0.431 |
| **Duration of disease from the beginning of treatment**  **(Days, Mean ± SD)** | 9.9 ± 5.5 | 18.1 ± 9.5 | <0.001 | 0.828 | 0.797 | 0.860 |
| **Rate of hospitalization-no (%)** | 11 (3.05) | 53 (29) | <0.001 | - | - | - |
| **Duration of Hospitalization when occurred**  **(Days, Mean ± SD)** | 0.2 ± 1.3 | 1.8 ± 3.2 | <0.001 | 0.074 | 0.038 | 0.147 |

No sign of severe side effects related to Xagrotin was observed. The only dose-dependent side effects were very mild diarrhea and allergic reaction in form of temporary skin rash. Skin rash was reported by two patients (2/361, 0.55%) in the study group. Mild diarrhea that was reported by less than 5% (n: 18) of patients was useful in some cases and decreased respiratory distress in some patients.