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Evaluating the Efficacy of Tasquinimod in Covid-19

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Abstract : Background: Quite disturbing is the huge public health impact of COVID-19: As at today [25th March 2021, the COVID-19 global burden shows over 123 million cases and over 2.7 million deaths worldwide. Rationale: Recent evidence shows calprotectin's potential as a therapeutic target, stating that tasquinimod, from the Quinoline-3-Carboxamide family is capable of blocking the interaction between calprotectin and TLR4. Hence preventing the cytokine release syndrome, that heralds the functional exhaustion in COVID-19. Early preclinical studies showed that tasquinimod inhibit tumor growth and prevent angiogenesis/cytokine storm. Phase I – III clinical studies in prostate cancer showed it has a good safety profile with good radiologic progression free survival but no effect on overall survival. Rationale/hypothesis: Strategic endeavors have been amplified globally to assess new therapeutic interventions for COVID-19 management – thus the clinical and antiviral efficacy of tasquinimod in COVID-19 remains to be explored. Hence the primary objective of this trial will be to evaluate the efficacy of tasquinimod in the treatment of adult patients with severe COVID-19 infections. Therefore, I hypothesise that among adults with COVID19 infection, tasquinimod will reduce the severe respiratory distress associated with COVID-19 compared to placebo, over a 28-day study period. Method: The setting is in Europe. Design – a randomized, placebo-controlled, phase II double-blinded trial. Trial lasts for 28 days from randomization, Tasquinimod capsule given as 0.5mg daily 1st fortnight, then 1mg daily 2nd fortnight. I0 outcome - assessed using six-point ordinal scale alongside eight 20 outcomes. 125 participants to be enrolled, data collection at baseline and subsequent data points, and safety reporting monitored via serological profile. Significance: This work could potentially establish tasquinimod as an effective and safe therapeutic agent for COVID-19 by reducing the severe respiratory distress, related time to recovery, time on oxygen/admission. It will also drive future research – as in larger multi-centre RCT.

Keywords : Calprotectin, COVID-19, Phase II Trial, Tasquinimod
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