

## The Impact of the COVID-19 Pandemic on Recruitment for the PERK 2 Clinical Trial

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**INTRODUCTION:** The COVID-19 outbreak created substantial challenges for conducting clinical trials. Many trials were halted because of the epidemic, and data collection was restricted in trials that were not stopped. The aim of this study is to examine how COVID-19 affected participant recruitment in an orthopaedic clinical trial that began before COVID-19 and is slated to complete recruitment December 2023.

**METHODS:** The PrEvention of posttraumatic contractuRes with Ketotifen 2 (PERK 2) is an ongoing Phase III randomized controlled trial which commenced in June 2019 (ClinicalTrials.gov NCT03582176). It is investigating the efficacy of Ketotifen Fumarate compared to placebo in reducing elbow joint contracture severity in an adult population following operative management of elbow fractures. Recruitment was halted by the sponsor March 16, 2020, and the return to recruitment was dictated by local site regulations. Trial recruitment was examined for trends pre-COVID-19 (June 01, 2019 – March 16, 2020), during-COVID-19 restrictions (March 17, 2020 – November 30, 2020), and post-COVID-19 restrictions (December 1, 2020 – May 31, 2023).

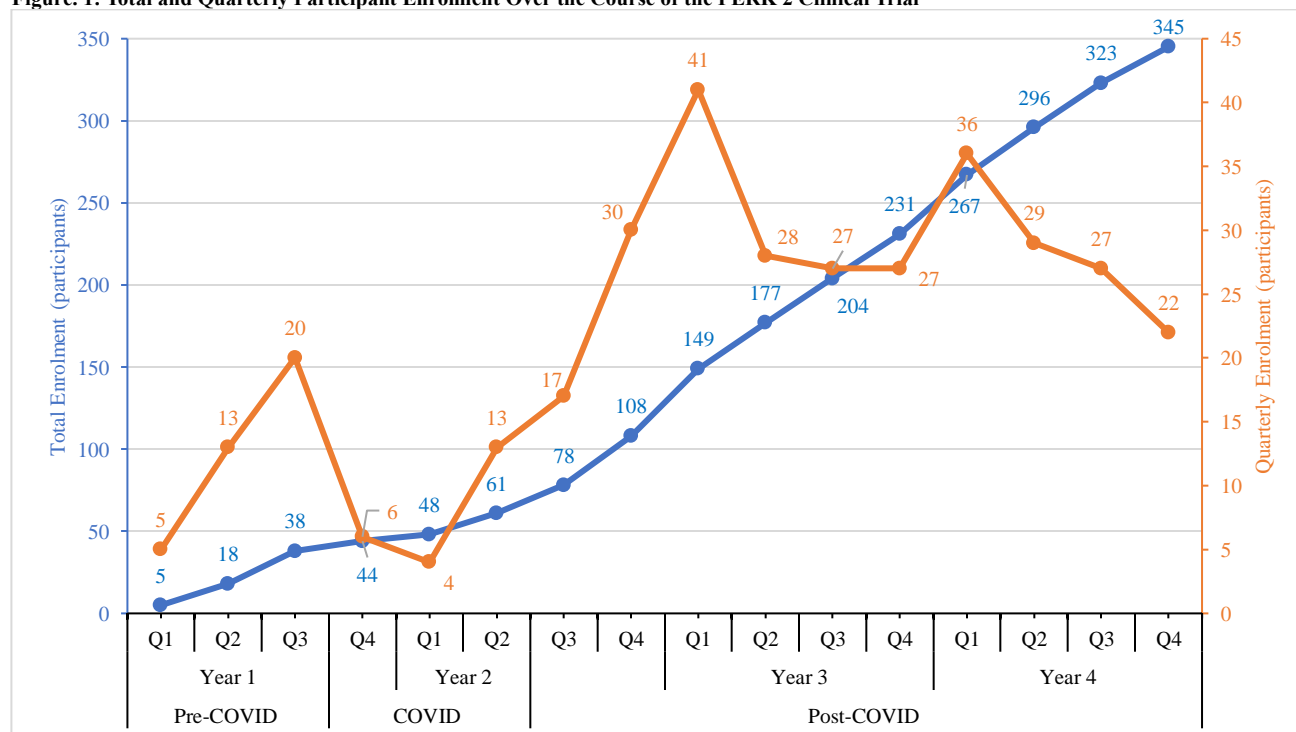
**RESULTS:** The trial had fifteen sites in Canada and the United States, with ten sites (66.7%) recruiting participants pre-COVID-19 and an additional five sites (33.3%) enrolling participants after COVID-19 restrictions. Between June 2019 and May 2023, 345 participants were enrolled in the PERK 2 trial (Figure 1). After a steady increase in quarterly recruitment in the first three quarters (pre-COVID-19), there was a dramatic decrease in the quarterly recruitment rate for the next three quarters (COVID-19, Figure 1). There was no participant enrolment in April and May of 2020 due to COVID-19 restrictions. In the post-COVID-19 period, trial recruitment returned to and then exceeded pre-COVID in the next three quarters reaching a trial quarterly high of 41 participants in year 3, quarter 1 (Figure 1). Forty-four participants (12.75%) were recruited prior to COVID-19, 17 (4.93%) during COVID-19, and 284 (82.32%) post COVID-19. The average quarterly participant recruitment/site was 1.27, 1.20, and 1.87 pre COVID-19, during COVID-19, and post COVID-19, respectively.

**DISCUSSION:** As expected, COVID-19 restrictions dramatically affected participant recruitment. April and May 2020 had no recruitment, and from June to November 2020 the original 10 sites returned at different times reflecting local regulations. The marked increase in participant enrollment post-COVID resulted from the elimination of recruitment restrictions and the addition of 5 more sites. The lower rates of recruitment following the quarterly high of 41 in year 3, quarter 1 were due to challenges in replenishing investigational product, local site restrictions, study personnel health, and potentially seasonal injury rate differences.

**CLINICAL SIGNIFICANCE:** Despite the disruption and challenges caused by the COVID 19 pandemic, the PERK 2 clinical trial study persevered and improved post-COVID enrolment rates. Maintaining active participant follow-up during COVID-19 restrictions kept the momentum at the 10 active sites, while adding new sites after COVID-19 to the already active sites enhanced recruitment. This underlines the need of having contingency plans when designing studies to minimize the effects of disruptions to participant enrolment and data gathering.

IMAGES AND TABLES:

**Figure 1: Total and Quarterly Participant Enrolment Over the Course of the PERK 2 Clinical Trial**



Note: Q1: June – August; Q2: September – November; Q3: December – February; Q4: March – May.