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2020

Study Title

Assessment of Deviations for HPCs Obtained during COVID-19 (ADHOC): Evaluating the Impact of the COVID-19 Pandemic on Cellular Therapy Products and Laboratory Processes

Study Description

The COVID-19 pandemic has resulted in substantial changes in cellular therapy product procurement and processing. The global impact of COVID-19 on travel has affected transportation times and storage conditions of allogeneic hematopoietic progenitor cell (HPC) products, and the unclear impact of COVID infection on products emerged as a potential concern. It is known that prolonged storage times and higher temperatures can negatively impact in vitro quality metrics of HPC products, but the impact on in vivo engraftment in patients is not established. Requirements and/or recommendations for allogeneic products to be cryopreserved also has potentially impacted cellular therapy laboratory workloads, as the number of products requiring cryopreservation has potentially increased while the number of staff has not changed. Our hypothesis that the changes in allogeneic cellular therapy product practices necessitated by the COVID-19 pandemic has had substantial impact on cellular therapy laboratory processes and cellular therapy product quality will be tested with the following specific aims:

1) Assess the impact that process changes have had on in vitro and in vivo allogeneic cellular therapy product quality metrics.

Data will be collected regarding the time from product collection to receipt and cryopreservation to determine if times have increased during the COVID-19 pandemic. Quality metrics to be collected include WBC and CD34 counts in the product before and after freezing, as well as in vivo ANC and platelet engraftment.

2) Assess the impact of cryopreservation requirements on the CTL workload capacity.

Data will be collected regarding number of staff, total numbers of products processed and number of products cryopreserved. This could be important to understand if labs capacity could be impacted by staffing volume changes in the event of staff being affected directly by COVID-19 exposure or infection.

Data will be collected for two time periods, one defined as before the COVID-19 pandemic and one defined as during the COVID-19 pandemic. This will allow for statistical analysis to be paired for each institution and allow for normalization

Analysis of data collected will help inform the cellular therapy community regarding the impact of the COVID-19 pandemic on cellular therapy laboratories and cellular therapy products and provide information that could impact patient care. The information from this project could lead to identification of potential opportunities for process improvement that could allow cellular therapy laboratories to adapt to ongoing or new situations that necessitate.

From early March 2020, national and international donor registries and advisory organisations began to strongly recommend that allogeneic donations be frozen to ensure that the required dose of stem cells was available to transplant centres before the start of patient conditioning. Given the fundamental change to the standard process of issuing fresh cells on a just-in-time basis, we would like to audit/compare product attributes in the periods before and after your laboratory began to freeze allogeneic donations (related and unrelated) on a routine basis in response to these recommendations.

Study Status

Completed

Publication Number

163

Teams

CT

Study Leaders

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