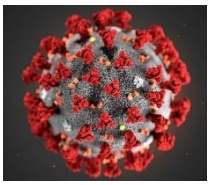
COVID-19 BMT

LAY SUMMARY OF STUDY RESULTS



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GENERAL INFORMATION

Study title

A retrospective and prospective non-interventional study to evaluate the role of immune and inflammatory response in recipients of allogeneic haematopoietic stem cell transplantation (SCT) affected by COVID-19 infection.

Who carried out the research?

Great Ormond Street Hospital (GOSH) sponsored the study. The IMPACT Partnership managed the data and delivered the study.

Funding was provided by Bristol Myers Squibb, the National Institute of Health Research (NIHR) Great Ormond Street Hospital Biomedical Research Centre, and the IMPACT Partnership. The IMPACT Partnership funders are Anthony Nolan, Leukaemia UK, and NHS Blood and Transplant.

What public involvement was there in the study?

This study collected data on 100 patients who had previously had a stem cell transplant with cells from a donor, and had since tested positive for COVID-19. All of the patients provided information about their general health, their transplant, and their medical history. Patients provided follow-up information at two time-points, 30 days and 100 days after their COVID-19 infection.

Where and when did the study take place?

Patients were recruited from 16 hospitals across the UK between May 2020 and June 2021. The final patient visit was in September 2021. The study took place in both adult and children's hospitals.

Study start date: 4th May 2020

Study end date: 10th September 2021

Why was the research needed?

When the study began, there was very little information available on the effect of COVID-19 infection in patients who have received a stem cell transplant. The researchers wanted to know more about how the immune system of a stem cell transplant patient might influence how they respond to a COVID-19 infection. The study was needed to gather more information on the medical effects of COVID-19 on this patient group, and their immune responses to the infection. Improving the understanding of COVID-19 in these patients might help to find out which treatment options to offer to stem cell transplant patients who are infected in the future.

What were the main questions studied?

The main aims of this study were to:

- understand what happens to stem cell patients who get a COVID-19 infection, and to look at their medical outcomes
- investigate the effects of COVID-19 infection on the immune system of stem cell transplant patients

Other related questions were:

- whether taking drugs which weaken the immune system affects response to the COVID-19 infection
- how many patients end up needing equipment to help with their breathing
- whether any patients develop a severe inflammatory condition
- how many patients still test positive for COVID-19 after 30 days

WHO PARTICIPATED IN THE STUDY?

Between April 2020 and September 2021, 100 patients were recruited. Patients could take part if they had received a stem cell transplant with cells from a donor and later tested positive for a COVID-19 infection.

Both children and adults of any age were included in this study, to look at the effect of COVID-19 infection in all age groups. The average age was 51 years old, and more male patients than female patients took part.

Eight patients were found not to be suitable for the study for a number of reasons including incorrect timing of COVID-19 infection. The rest were put into two patient groups:

- A 'Prospective cohort' group of ten patients, who were recruited within three days of their positive COVID-19 test and gave samples for research.
- A 'Retrospective cohort' group made up of the remaining 82 patients were recruited more than three days after their COVID-19 infection

PROSPECTIVE COHORT

- On average, patients in this group tested positive for COVID-19 eight months after their transplant.
- Seven (70%) of the ten patients were receiving drugs to weaken the immune system at the time of COVID-19 diagnosis.
- The most common stem cell donor type was a sibling donor.

RETROSPECTIVE COHORT

- On average, patients in this group tested positive for COVID-19 eleven months after their transplant.
- Forty (49%) of the 82 patients were receiving drugs to weaken the immune system at the time of COVID-19 diagnosis.
- The most common stem cell donor type was a sibling donor.

WHAT TREATMENTS OR INTERVENTIONS DID THE PARTICIPANTS TAKE/RECEIVE?

This was an observational study. Observational studies aim to find out what happens to people in different situations. The research team observe the people taking part and collect information on what happens to them, but they do not influence what treatments people have.

WHAT HAPPENED DURING THE STUDY?

All of the patients provided information about their general health, their transplant, and their medical history. Patients provided follow-up information at 30 and 100 days after their positive COVID-19 test. COVID-19 test results, the types of treatments given, and symptoms experienced were collected.

Any patients recruited within 72 hours of a COVID-19 positive test also provided blood samples for research. The blood samples were analysed to look at changes to the immune system of patients after a COVID-19 infection.

WHAT WERE THE RESULTS OF THE STUDY?

The study found a higher chance of dying in patients who were older, if COVID-19 diagnosis was closer to the time of transplant, and if equipment was needed to help with breathing.

PROSPECTIVE COHORT

The most common symptoms at COVID-19 diagnosis were a fever (70% of patients), a cough (50% of patients), and shortness of breath (40%).

Four patients (40%) needed additional oxygen to help with breathing, and one patient (10%) needed breathing support from an air pump. At 30 days after COVID-19 diagnosis, one patient (10%) had gone on to need a machine to breathe. Unfortunately, by day 30 three patients had died from COVID-19. There

were no further deaths between day 30 and day 100. The average time for a patient to test negative for COVID-19 was 52 days.

RETROSPECTIVE COHORT

At COVID-19 diagnosis, the most common symptoms were a fever (48% of patients), a cough (46% of patients), and shortness of breath (20%).

At the time they received a positive test, nine patients (11%) needed additional oxygen to help with breathing, and one patient (1%) needed a machine to breathe. Most patients (87%) did not need any help with their breathing. After 30 days, four patients (5%) had needed breathing support from an air pump and five patients (6%) had needed a machine to breathe.

Unfortunately, after 30 days 14 patients (17%) had died. Ten of these deaths (71%) were because of COVID-19. After 100 days, a total of 21 patients (26%) had died. This included 14 deaths (67%) due to COVID-19. The average time for a patient to test negative for COVID-19 was 37 days.

HOW HAS THIS STUDY HELPED PATIENTS AND RESEARCHERS?

The study adds to and supports previous research, which shows that COVID-19 in stem cell transplant patients can be severe and life threatening, especially for adults and those who have had their transplant more recently. This study has provided more information on how stem cell transplant patients respond to a COVID-19 infection, which was previously unknown.

Looking at the available patient samples, patients do not seem to have the same immune system response to COVID-19 infection that has been seen in people who do not have a weakened immune system. More research will be needed to confirm this.

DETAILS OF ANY FURTHER RESEARCH PLANNED

Stem cell transplant patients might not share the immune system characteristics of the general population, so we need more studies to identify the best targets for treatment in this group of patients.

WHERE CAN I LEARN MORE ABOUT THIS STUDY?

ClinicalTrials.gov website: https://clinicaltrials.gov/ct2/show/NCT04349540

The IMPACT website: https://www.impactpartnership.org.uk/the-trials/covid19-bmt/

The Anthony Nolan website: https://www.anthonynolan.org/blog/2020/05/19/clinical-trial-announced-study-impact-severe-covid-19-infection-patients-who

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