

<b>Trial title</b>	Renal rescue immunosuppression following heart transplantation
<b>R&amp;D PIN:</b>	2008TP001
<b>EudraCT reference</b>	2007-003649-34
<b>Sponsor(s)</b>	Manchester University NHS Foundation Trust
<b>Chief Investigator</b>	Professor Nizar Yonan

The above Clinical Trial of an Investigational Medicinal Product (CTIMP) was conducted at University Hospital of South Manchester (now known as Manchester University NHS Foundation Trust) from 13/08/2008 to 31/01/2012.

The primary objective was to investigate the difference in renal function (GFR) between the groups at 6 months. The secondary objectives were:

1. Investigate efficacy: Renal function at 12 months, treated acute rejection episodes
2. Investigate safety: Adverse events (including infection, haematological and gastrointestinal effects, bleeding, skin rash, pneumonitis, any cause of hospitalisation for treatment death), cardiovascular risk factors and standard laboratory assessments.

A total of 17 participants were recruited but two participants withdrew and another two were lost to follow up.

There was one serious adverse event in the trial in 2009 but it was assessed by a clinician as being unrelated to the Investigational Medicinal Product.

The recruitment target for the trial was 56 but only 17 participants were recruited. As such, due to recruitment difficulties, the trial was withdrawn by the sponsor. Analyses were not conducted and the results of the trial were not published.

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Date: 30th March 2020

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