

Trial title	An observational study of i) mini-area-under-the-curve (mini-AUC) estimation of exposure to mycophenolic acid (MPA) in heart transplant and lung transplant recipients on mycophenolate mofetil (MMF) or Mycophenolate Sodium (Myfortic) ii) utility of salivary measurements of MPA levels in heart & lung transplant recipients.
R&D PIN	2003TP001
EudraCT reference	2007-002201-53
Sponsor(s)	Manchester University NHS Foundation Trust
Chief Investigator	Professor Colm Leonard

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 2007 to 19/07/2010. This was an observational study of MPA levels in peripheral blood and saliva of heart and lung transplant patients. This study was observational in terms of watching clinical course (rejection, infection including bacterial, viral & fungal episodes) and also correlating levels with side effects such as nausea/vomiting/diarrhoea (all patients to receive a questionnaire for GI side effects at weekly intervals for first month and monthly thereafter).

The study group included adult heart and lung transplant patients aged 18-65; who were on triple immunosuppressant therapy including Mycophenolate Mofetil or Mycophenolate Sodium. The doses of Mycophenolate Mofetil or Mycophenolate Sodium were to be unchanged for the previous 2 days prior to the study. At the time of the study the patient had to be on stable dose of Mycophenolate Mofetil and Mycophenolate Sodium with no serious gastrointestinal problems.

The primary endpoint was to assess for correlation between drug exposure as measured by area under the curve and patient symptoms of Leukopenia, Rejection, and GI Intolerance.

The trial was terminated early on 19/07/2010 due to non-safety related issues. Insufficient data was collected to provide meaningful analysis; therefore no publications resulted from the trial.

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