Trial title	Does N-Acetylcysteine (Parvolex) prophylaxis reduce the incidence of renal impairment after on pump Coronary artery bypass surgery? A prospective randomised controlled trial
R&D PIN	2006AN007
EudraCT reference	2006-006815-62
REC reference	07/Q1403/17
ISRCTN reference	ISRCTN71629284
Sponsor	Manchester University NHS Foundation Trust
Chief Investigator	Dr Donna Greenhalgh

The above referenced single-centre, double-blind, randomised, placebo controlled, phase IV Clinical Trial of an Investigational Medicinal Product (CTIMP) was conducted at University Hospitals of South Manchester NHS Foundation Trust (now known as Manchester University NHS Foundation Trust) from approx. May 2007 to 08/09/2009. The medical condition under investigation was renal impairment after coronary artery bypass surgery.

The primary objective of the trial was to determine whether prophylactic use of N-Acetylcysteine decreases the incidence of renal impairment after cardiac surgery. The secondary objection was to determine whether prophylactic N-Acetylcysteine has effect on the length of ICU/HDU stay.

The primary endpoint for the trial was the serum creatinine levels in the first 48 hours. The trial aimed to recruit 224 adult participants who underwent elective coronary bypass surgery at Wythenshawe Hospital.

Between 30-40 participants were recruited to the trial and no Serious Adverse Events occurred.

Following a temporary halt of the trial implemented 29th May 2009, the decision was taken by the Sponsor to withdraw the trial on 8th September 2009 due to staffing and resourcing issues. No participants were receiving treatment at the time of the early termination.

Name: LYNNE WEBSTER Date: 16 Jan 2020

Signature: L Webster