

Trial title	Role of Poly Unsaturated Fatty Acids (PUFAs) in the management of Paroxysmal Atrial Fibrillation (PAF)
R&D PIN	2006CD013
EudraCT reference	2006-006863-22
Sponsor(s)	Manchester University NHS Foundation Trust
Chief Investigator	Dr Christopher Lang

The above double blind, randomised, controlled phase IV 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 29/10/2007 to 14/09/2009. The aim of this trial was to assess the effect of oral supplementation of PUFAs on the frequency and duration of AF episodes in patients known to have paroxysmal atrial fibrillation with a high (=10%) AF burden and who already have a pacemaker in situ.

The primary endpoint was the number of mode switch episodes during pacemaker check (a surrogate for AF) as a measure of AF burden.

The secondary Objective was to evaluate the role of fish oils on inflammatory markers and co-relate the relationship to AF burden.

The trial was terminated early on 14/09/2009. The IMP manufacturer sold the company and the new owners did not produce the IMP with the same specifications. Seven participants had been recruited so far and all were informed of the decision to terminate the study. Their continual medical care was arranged to ensure uninterrupted care. In view of the small number of participants recruited, no assessment could be made in relation to the effectiveness of the IMP in this indication.

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Date: 29 Jan 2020

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