University Hospitals Dorset
NHS Foundation Trust

Trial Title:	Isoprenaline infusion as a method of induction of Atrial Fibrillation; A randomised controlled trial investigating the use of Isoprenaline to induce an episode of atrial fibrillation (IsoAF)
IRAS ID:	138811
REC Reference:	14/SC/1171
EudraCT Number:	2014-002290-11
Chief Investigator:	Dr John Paisey
Sponsor:	Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust (now University Hospitals Dorset NHS Foundation Trust)

This Clinical Trial of an Investigational Medicinal Product began at Royal Bournemouth Hospital in February 2015 and ended on 30th March 2017. John Radcliffe Hospital, Oxford, was also a participating site. The aim of the trial was to establish whether an infusion of the drug isoprenaline induce an episode of the abnormal heart rhythm, atrial fibrillation. A total of 188 participants were recruited to the trial.

The trial was inspected as part of a routine Medicines and Healthcare Products Regulatory Agency (MHRA) Good Clinical Practice (GCP) inspection at the Royal Bournemouth Hospital in July 2018 as the sponsor for the study. It was identified that the control mechanisms in place to protect the blinding for the study were insufficient. The study cannot therefore be described as being conducted in a double-blind fashion as is described in the protocol.

The Research Sponsorship Group are concerned about the data obtained for the trial and do not believe it to be of sufficient quality to allow reporting of results to the regulatory bodies or the public. Further, a large number of participants had protocol deviations recorded for them due to only one or in some cases no infusions being delivered because of perceived time pressures with the cardiac laboratories. In total, only 69 participants completed two infusions.

An abstract was previously published with The Physiological Society which has since been redacted following sponsor review of the data (High-dose Isoprenaline Infusion as a method of arrhythmia induction in man; a placebo controlled experiment in humans with varying arrhythmic risk - The Physiological Society (physoc.org)).

Following the MHRA GCP inspection in 2018, robust processes were put in place to ensure appropriate sponsor oversight and monitoring of studies for which the Trust is the sponsor. In addition, the relevant SOPs are currently being reassessed following a Trust merger to ensure that the best practices from both organisations are incorporated.

In the corresponding results upload to EudraCT, any field completed with ‘99999’ indicates that the data is unavailable.