

# Clinical trial targets acute respiratory distress syndrome with cholesterol drug

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Queen's University and NUI Galway and are leading a clinical trial to investigate the possibility that statins, a drug commonly used to combat cholesterol, might help patients with acute severe respiratory failure.

150 patients have been recruited into the trial, which is being run in collaboration with the Irish Critical Care Trials Group, across multiple intensive care units on the island of Ireland, and in England and Scotland, with a target number of 540 patients.

The research is being funded by the Health Research Board, and the Efficacy and Mechanism Evaluation programme which is funded by the Medical Research Council and the National Institute for Health Research (NIHR), with contributions from the CSO in Scotland, NISCHR in Wales and the HSC R&D, Public Health Agency in Northern Ireland, and is managed by the NIHR.

When people become critically ill, for various reasons including major surgery or following injury in a road traffic accident, or infections such as H1N1 influenza, their lungs often fail, which is termed 'Acute Respiratory Distress Syndrome'. This condition, which is primarily caused by the body's immune system response to the injury, is common, can affect any age group, and is often fatal. Furthermore, even after recovery from [lung injury](#), patients subsequently experience a poorer quality of life. Many survivors of this condition are unable to return to work or look after themselves.

"Unfortunately, to date there is no effective treatment for this lung injury", said Professor John Laffey who is Professor of Anaesthesia at NUI Galway and Consultant Anaesthetist at Galway University Hospitals. "We are investigating if the drug simvastatin, commonly used to treat high [cholesterol](#), is safe and effective in the treatment of this lung injury. A unique feature of this study is that it is a study generated from Irish research efforts, and is an Irish-led multi-national study, being conducted across the island of Ireland, and also in intensive care units in England and Scotland."

Professor Laffey continued: "This study builds on a series of studies using simvastatin, including a smaller clinical trial funded by the Health and Social Care Research and Development Division, Public Health Agency for Northern Ireland and REVIVE, carried out by Professor Danny McAuley and his team in the Belfast Health and Social Care Trust, who are our partners in this study. These studies offer considerable hope that simvastatin might help sufferers from this devastating disease. The study may take up to five years to complete, but if simvastatin is effective, it would help save the lives of these sufferers, improving the quality of life of survivors and potentially reduce costs, by reducing time spent in intensive care units."

The study team comprises experts in study design based at the HRB Galway Clinical Research Facility and at the Clinical Research Support Centre in the Belfast Health and Social Care Trust, as well as senior doctors who work in critical care units, and experts in acute lung injury.

Professor Danny McAuley, who is Professor of Intensive Care Medicine at Queen's University Belfast and Consultant Intensivist at the Royal Victoria Hospital, explained: "We will also take blood samples to measure markers of inflammation which will allow us to determine if simvastatin can reduce the immune response which causes the lung injury. In addition, we will determine how severe the damage to the

patients' lungs is, and how fast they recover."

People will be randomly divided into two groups; one group will be given the active drug and the other a placebo. This design means that any difference in the experience of patients will be due to whether or not they received simvastatin and not to any other difference that could influence the outcome of treatment.

Frank Giles, who is Professor of Cancer Therapeutics at NUI Galway, is also Director of the HRB Clinical Research Facility at NUI Galway, which is helping co-ordinate the clinical trial in Ireland: "Participants in this trial are helping address a vital and difficult medical problem. This study is typical of an increasing number of multi-center trials that are possible because of increasing collaboration between Ireland's HRB-funded Clinical Research Facilities. The studies involve patients with a very broad spectrum of health challenges. The conduct of these studies, which involve our patients and their families, community health-care staff, hospitals, research institutes and industry partners, improves health care and ensures that Ireland continues to make a significant increasing contribution to global medical progress."

Provided by Queen's University Belfast

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