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Ground-breaking €34 million project to develop better test for liver disease

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A pioneering European research project aims to lead to new diagnostic tests to assess patients with non-alcoholic fatty liver disease (NAFLD) and identify those most at risk for developing severe inflammation and liver scarring.

Liver Investigation: Testing Marker Utility in Steatohepatitis (LITMUS) funded by the European Innovative Medicines Initiative 2 Joint Undertaking, brings together clinicians and scientists from prominent academic centres across Europe with companies from the European Federation of Pharmaceutical Industries and Associations (EFPIA). Their common goals are developing, validating and qualifying better biomarkers for testing NAFLD.

The €34 million project is co-ordinated by Newcastle University, working closely with the lead EFPIA partner, Pfizer Ltd. LITMUS will include 47 international research partners based at leading international universities and some of the world's largest pharmaceutical companies.

Affecting 20 – 30 % of the population worldwide, NAFLD is caused by a build-up of fat in the liver cells, which leads to inflammation, scarring of the liver and ultimately cirrhosis. It is strongly linked to obesity and type 2 diabetes.

Although many people have NAFLD, less than one in 10 will come to harm as a result1 . The challenge is to identify those people that will be most severely affected and are going to progress to liver cirrhosis or cancer so that appropriate care can be provided earlier. At present this requires a liver biopsy, which can only be done in specialist hospitals, so there is a need for better diagnostic tools.

Professor Quentin Anstee, from Newcastle University's Institute of Cellular Medicine and Consultant Hepatologist at Newcastle Hospitals NHS Foundation Trust, is co-ordinating the LITMUS consortium.

He said: "Non-alcoholic fatty liver disease is already the most common underlying cause of liver transplant in the USA and, with the obesity epidemic in Europe, we are very close behind.

"LITMUS will unite clinicians and academic experts from centres across Europe with scientists from the leading pharmaceutical companies, all working together to develop and validate new highlyaccurate blood tests and imaging techniques that can diagnose the severity of liver disease, predict how each patient's disease will progress and monitor those changes, better or worse, as they occur.

"Lack of easy and accurate diagnostic tests means that many patients go undiagnosed until late in the disease process. It has also held-back efforts to develop new medical treatments for NAFLD. Availability of better diagnostic tests will help us to target care at an early stage of disease to the people who are going to be most

severely affected. It will also help us to develop more effective medical treatments for NAFLD and to run the clinical trials that the regulatory agencies need so that they can licence these medicines to be prescribed by doctors."

Professor Chris Day, Vice-Chancellor and President, Newcastle University who is himself a Consultant Hepatologist with an international reputation and part of the research team, added: "Tackling Nonalcoholic fatty liver disease is a major public health challenge and the award of such a large grant from the EU, allowing us to bring together pharma and academia in this way, gives us real hope of making significant advances in the diagnosis and treatment of this increasingly common and often devastating disease."

Julia Brosnan, Senior Director of External Collaborations & Scientific Alliances, Pfizer, who also serves as the industry project lead for LITMUS, said: "This is an exciting project and we look forward to working with the other LITMUS partners to develop new diagnostic tests for NAFLD, which is too often undiagnosed in patients. We hope the results of this project will help change that."

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777377. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

Living with NAFLD – Yvonne's story

Yvonne Gray, 62, was diagnosed with NAFLD in 2011. A retired headteacher who lives in Fulwell, Sunderland, she is now a governor of the national adult liver patient support group, LIVErNORTH:

"I do consider myself really fortunate in that it was by chance my liver disease was eventually diagnosed, when my "mildly abnormal" liver function tests were picked up by a consultant treating me for a Vitamin D deficiency and he then referred me to a hepatologist.

"By the time I was referred to the Freeman Hospital Liver Unit in Newcastle I had Non-Alcoholic Fatty Liver Disease, specifically NASH, Stage 3 Liver Disease with significant fibrosis.

"It is interesting that even now my liver function tests are still presenting as 'mildly abnormal', thereby not appearing to trigger any major cause for concern. However, my two liver biopsies say something totally different.

"It is exciting to hear about this new collaboration. I would be delighted if there could be a simple blood test. The alternative, a liver biopsy, can involve a stay in hospital, is uncomfortable and can be painful."

NAFLD – the facts

A healthy liver should contain little or no fat, however, it's thought that 1 in every 3 people in Europe has some degree of NAFLD, where there is an excessive amount of fat accumulation in the liver. While this doesn't always cause harm, it can develop into an inflammatory form of the condition called steatohepatitis (NASH) that in turn causes fibrous scar tissue to form in the liver and leads to serious liver damage including cirrhosis in some patients. It can also increase the risk of cancer in the liver, heart attack and stroke.

ENDS

REFERENCE

1 Younossi, Z. M. et al. The economic and clinical burden of nonalcoholic fatty liver disease in the United States and Europe. Hepatology 64, 1577-1586, doi:10.1002/hep.28785 (2016).

NOTES FOR EDITORS:

www.litmus-project.eu
www.imi.europa.eu
Professor Quentin Anstee:
http://www.ncl.ac.uk/icm/people/profile/quentinanstee.html#background
PHOTOS of Co-ordinating centre lead, Professor Quentin Anstee (in the lab) and of patient Yvonne Gray – https://drive.google.com/open?id=1ks0hZ1CIdT9is0uzOpigmbdzCBgSs7fH

Twitter: @LITMUS_IMI

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