Biological bypass shows promise in coronary artery disease

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A new gene therapy that targets the heart and requires only one treatment session has been found safe for patients with coronary artery disease, according to a successful trial carried out in Finland. Enhancing circulation in the oxygen-deficient heart muscle, the effects were visible even one year after the treatment.

The randomised, blinded, placebo-controlled phase 1/2a trial was carried out in collaboration between the University of Eastern Finland, Kuopio University Hospital and Turku PET Centre as part of the Centre of Excellence in Cardiovascular and Metabolic Diseases of the Academy of Finland.

The biological bypass is based on gene transfer in which a natural human growth factor is injected into the heart muscle to enhance vascular growth. The trial was the first in the world to use a novel vascular growth factor that has several beneficial effects on circulation in the heart muscle. The trial also developed a novel and precise method for injecting the gene into the oxygen-deficient heart muscle area. A customised catheter is inserted via the patient's groin vessels to the left ventricle, after which the gene solution can be injected directly into the heart muscle. The method is as easy to perform as coronary balloon angioplasty, which means that it is also suitable for older patients and patients who are beyond a bypass surgery or other demanding surgical or arterial operations.

The biological bypass constitutes a significant step forward in the

development of novel biological treatments for patients with severe coronary artery disease. A new blood test biomarker was also discovered, making it possible to identify patients who are most likely to benefit from the new treatment.

The biological bypass was developed by Academy Professor Seppo Ylä-Herttuala's research group at the A.I. Virtanen Institute for Molecular Sciences of the University of Eastern Finland. At the Kuopio University Hospital Heart Centre, Professor Juha Hartikainen was responsible for the trial.

Securing six million euros of funding from the European Union, research into the biological bypass will continue, and a new phase 2b trial will start at Kuopio University Hospital in early 2018. This trial will also include five other cardiology clinics from Denmark, the UK, Austria, Spain and Poland. The multi-centre trial will be coordinated by the Kuopio University Hospital Heart Centre, and the gene therapy drug will be manufactured in the clean room facilities of FinVector Therapies Ltd. in Kuopio.

More information: Juha Hartikainen et al. Adenoviral intramyocardial VEGF-DΔNΔC gene transfer increases myocardial perfusion reserve in refractory angina patients: a phase I/IIa study with 1-year follow-up, *European Heart Journal* (2017). DOI: 10.1093/eurheartj/ehx352

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