Title: HF 22: Novel Patch Infusor Device & Subcutaneous Furosemide in Pts with HF
Participants: Dr Joanna Osmanska
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- My name is Joanna Osmanska. I'm a Clinical Research Fellow at the University of Glasgow. And I present results of two early phase clinical trials, investigating use of subcutaneous furosemide in patients with heart failure.

Importance of this Study

Dr Osmanska: So most important things that we have used in new preparation of subcutaneous furosemide, which is pH neutral. It is highly concentrated preparation, containing 30 milligrammes of furosemide in one ml. So that allows to administer dose of 80 milligrammes of furosemide in 2.7 millilitres. But also we presented the results of a first in man use of novel subcutaneous patch infuser pump, which has been specifically designed to administer the treatment.

Study Design and Eligibility Criteria

Dr Osmanska: The first trial was a PK/PD trial, it was a phase one trial, a single dose trial, randomised controlled trial with a crossover design. And in this trial, 80 milligrammes of subcutaneous furosemide was administered using conventional infusion pump.

The active comparator was 80 milligrammes of intravenous furosemide administered as a bolus. The inclusion criteria included patients with a heart failure, any ejection fraction and NYHA class II and III.

In a second trial we used the same preparation of subcutaneous furosemide. It was a phase one single dose trial, where 80 milligrammes of subcutaneous furosemide was administered using novel patch infuser device.

This trial included patients admitted to the hospital with decompensated heart failure who require treatment with intravenous furosemide at a dose of 40 milligrammes or more. We've accepted patients with any ejection fraction.

Key Findings

Dr Osmanska: The key findings in terms of a PK/PD study is that the subcutaneous furosemide in comparison to intravenous furosemide achieved a bioavailability of 112%. The natriuresis and diuresis were comparable to the clinical efficacy of subcutaneous furosemide with similar to that of intravenous furosemide.

In the patch infuser pump, we've proven that the device is safe to use and there is no device failures. The diuresis effect was similar to that in PK/PD trial, and natriuresis effect was of 97 mmol per litre, which is above recommend that 70 mmol per litre as per EFC statement. We've also proven that the device is well tolerated by the patient.

Take-Home Messages

Dr Osmanska: Novel preparation of subcutaneous furosemide has been prone to have similar clinical efficacy in terms of a natriuresis and diuresis to intravenous furosemide administered as a bolus. In preliminary phase one trial, we've also shown that 80 milligrammes of subcutaneous furosemide administered with a patch infusion pump has been safe and well tolerated by the patients.

Next Steps

Dr Osmanska: The next steps will be a randomised controlled trial investigating new treatment strategy, subcutaneous furosemide in comparison to intravenous furosemide, and we'll plan to start this trial in June 2022.