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| **Trial title** | Eplerenone in Metabolic Syndrome: An Investigation into the Effects of Eplerenone on Perivascular Adipose Tissue and Small Artery Tone in Obesity |
| **R&D PIN** | R01323 |
| **EudraCT reference** | 2010-022308-34 |
| **REC Reference** | 10/H1010/59 |
| **Sponsor** | Manchester University NHS Foundation Trust |
| **Chief Investigator** | Dr Adam Greenstein |
| **Principal Investigator** | Dr Reza Aghamohammadzadeh |

The above referenced single centre, open-label, Clinical Trial of an Investigational Medicinal Product (CTIMP) was conducted at Central Manchester University Hospitals NHS Foundation Trust (now known as Manchester University NHS Foundation Trust) from 31/08/2011 to 01/12/2012. The trial investigated the use of a frequently prescribed medication (Eplerenone) in a condition which it was not licensed for. Eplerenone blocks the action of the hormone, aldosterone, which is thought to damage blood vessels in obesity and cause damage (fibrosis) in the heart. For this reason the study team wished to see whether administration of Eplerenone could improve blood vessel and adipose tissue health in obese patients.

The trial had primary and secondary aims:

1. To determine whether Eplerenone is able to statistically significantly improve the effect of perivascular adipose tissue (PVAT) on the function of subcutaneous small arteries taken from patients with obesity and metabolic syndrome.
2. To determine whether treatment with Eplerenone in patients with obesity and metabolic syndrome is able to improve:
    - Basal Metabolic rate
    - Insulin resistance (HOMA-IR) and Insulin sensitivity (HOMA-B)
    - Bio-impedance
    - Circulating adipokine levels: adiponectin and leptin levels,
    - Markers of systemic inflammation (highly sensitive CRP) and IL-6 (a surrogate measure of adipose tissue inflammation in obesity)
    - Left ventricular mass and diastolic dysfunction

The study team aimed to recruit 30 obese patients with metabolic syndrome (aged 30-65) where, following the obtaining of informed consent, they would receive an oral administration of 25mg Eplerenone once daily (increased to 50mg once daily after 14 days) for 12 weeks. The effects of Eplerenone were to be studied by taking gluteal fat biopsies before and then after 12 weeks of treatment. Overall, the study consisted of six visits per participant.

Substantial amendment 1 was submitted to the regulatory authorities on 24/04/2012 which requested a temporary halt of the trial whilst the Principal Investigator was on sabbatical in the USA. An alternative Principal Investigator or Co-Investigator could not be identified by the sponsor.

On 8th November 2012, the end of trial notification submission was made to the REC and MHRA. Following the implementation of substantial amendment 1 (temporary halt), the investigator returned to the UK but, due to changes made to clinical services within the Trust which would make it difficult to identify eligible participants, the sponsor took the decision to terminate the trial. As per the end of study notification documentation, no participants were recruited to the trial.

Name: LYNNE WEBSTER Date: 6th Dec 2019

Signature: L Webster Representing the sponsor