PAracetamol **T**reatment in **H**ypertension: Effect on **B**lood **P**ressure *Study* - **PATH-BP Study**

The **PATH-BP** Study is funded by a £140,000 grant from the British Heart Foundation. The study is based at the Western General Hospital in Edinburgh, and the chief investigator is Professor David Webb, Professor of Therapeutics at The University of Edinburgh, and Director of Edinburgh's European Society of Hypertension Excellence Centre.

Background

Hypertension (high blood pressure) is very common in the UK, affecting 1 in 4 adults. It is a major risk factor for heart attacks and strokes, which can result in death and serious disability. Anti-inflammatory pain-relieving drugs can increase blood pressure and, because of this, paracetamol (another pain relieving drug) is often suggested as an alternative. However, there is now some evidence that paracetamol may also increase blood pressure.

The **PATH-BP** study is designed to determine the effect of two weeks of paracetamol on blood pressure in patients with hypertension. We will compare the effects of paracetamol on blood pressure with that of a dummy tablet (placebo).

Study Design

We plan to recruit 100 participants with either treated or untreated hypertension. Each participant will then take 2 weeks of paracetamol and 2 weeks of placebo in a random order, with blood pressure being checked at the beginning and end of each 2-week period.

The study will recruit participants from hospital, through hypertension clinics at the Royal Infirmary and Western General Hospital, the ambulatory blood pressure service and general practices within NHS Lothian, with help from the Scottish Primary Care Research Network (SPCRN).

Major Inclusion/Exclusion Criteria

Inclusion criteria

- ≥18 years old, men or post-menopausal women (women with no periods for 12 months or more, or those who have had a surgical menopause).

- Treated hypertensive patients with an average daytime ambulatory blood pressure of <150/95mmHg on stable doses of one or more antihypertensive medication for 3 months, or untreated hypertensive patients with an average daytime ambulatory blood pressure with a systolic of ≥135 and/or a diastolic of ≥85 but <150/95.

Exclusion criteria

- History of recent active heart disease (myocardial infarction or chest pain within the last 6 months), heart failure, stroke, liver impairment (ALT/AST>50IU/L) or stage 3-5 chronic kidney disease.
- History of overdose or suicidal ideation
- Patients weighing <55kgs.
- Patients with chronic pain requiring treatment, with a known allergy to paracetamol, or concomitant use of NSAIDs, oral anticoagulants or corticosteroids.

Potential benefits of the study

This study should provide clear evidence of whether or not paracetamol directly effects blood pressure and help people with high blood pressure and their doctors understand better the safety of using paracetamol as a treatment for chronic pain.

Further information

For further information or if you are interested in taking part, please contact Ms Vanessa Melville, Clinical Research Centre, Western General Hospital, Edinburgh. Tel. 0131 537 2008. Email v.melville@ed.ac.uk.

Study reference number(s)

European Clinical Trials Database (EudraCT) number: 2013-003204-40
ClinicalTrials.gov Identifier (NCT number): NCT01997112
Research Ethics Committee Number: 13/ES/0087
Research Ethics Committee approval date: 17th September 2013