SDRN: Scottish Diabetes Research Network

Management of Clinically Significant Blood Pressure Measurements in a Clinical Trial

Clinical S.O.P. No. 38
Version 1

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CHIEF SCIENTIST OFFICE

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DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Louise Greig	

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1. Introduction

Blood pressure measurements are routinely taken as part of clinical trials and it is important that the findings are managed appropriately by the research team. A significant clinical finding is defined as a finding that is part of the research assessment and may have clinical significance requiring further investigation or treatment.

2. Objective

The purpose of this SOP is to outline the action that should be taken when a clinically significant blood pressure measurement is identified during a clinical trial, and where no specific action has been stipulated in the study protocol.

3. Responsibility

The well-being of study participants should be protected, and reported, at all times. Therefore, it is the responsibility of the study team to take appropriate action to ensure that any blood pressure results that may have clinical significance are managed appropriately.

4. Procedure

Before reporting a blood pressure reading as abnormal please check the following -

- The blood pressure monitoring device has been calibrated recently.
- The location where the measurements are being carried out is
  - quiet,
  - person was seated with their arm outstretched and supported,
  - no restrictive clothing and
  - correct size of blood pressure cuff was used.
- The preliminary steps to be taken before a blood pressure reading is taken have been adhered to.
  - The patient has not smoked, drunk coffee or alcohol for at least 30 minutes before the examination.
- Consider the possibility of the 'white coat' effect that could explain the high readings.

5. Action to be taken on clinically significant findings

- **Mean SBP $\geq$ 200mmHg or mean DBP $\geq$ 130mmHg.**
  - Participant will be informed of result.
  - If a study doctor is available then a management plan should be agreed with the doctor and participant.

- Where a study doctor is unavailable referral to Accident and Emergency department should be made.
- A letter to the GP will be prepared by the study nurse. The original will be sent to the patients GP, a copy given to the patient and another kept in the participants' study records.

- **Mean SBP ≥ 180mmHg or mean DBP ≥ 110mmHg**

  - Participant will be given a note of the blood pressure reading and advised to make an appointment to see their GP or practice nurse by the next working day.
  - The study nurse will inform the GP by telephone and by letter. One copy of the letter will be sent to the GP and a copy will be kept in the participants' study records.

- **Mean SBP ≥160mmHg or Mean DBP ≥100mmHg**

  - Participant will be given a note of the blood pressure reading and advised that they should contact their GP practice to discuss the results and seek a proper medical examination for themselves within the next 2-3 weeks.
  - The study nurse will inform the GP by letter. One copy of the letter will be sent to the GP and a copy kept in the participants' study records.

- In all cases the local Principal Investigator will be informed by email of the action taken.