

Clinical S.O.P. No.:27 Version 1.0

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DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Alison Sudworth	

1. Introduction

ICH GCP states that 'systems with procedures that assure the quality of every aspect of the trial should be implemented'. This SOP details the procedure to be followed to manage hypoglycaemia.

2. Background

Hypoglycaemia is a lower than normal level of blood glucose. It can be defined as "mild" if the episode is self-treated and "severe" if assistance by a third party is required. In a person with diabetes all documented blood glucose values below 4.0 mmol/l can be considered to represent hypoglycaemia.

Hypoglycaemia is the commonest side effect of insulin, and sulphonylureas, in the treatment of diabetes.

People experiencing hypoglycaemia require quick acting carbohydrate to return their blood glucose levels to the normal range. The quick acting carbohydrate should be followed up by giving long acting carbohydrate either as a snack or as part of a planned meal. All patients experiencing hypoglycaemia should be treated immediately. Where it is safe to do so a blood glucose measurement should be taken to confirm hypoglycaemia.

3. Objectives

The aim of this SOP is to describe the symptoms of hypoglycaemia and the action required to correct this condition in order to ensure the safety of patients involved in clinical research studies.

4. Responsibilities

It is the responsibility of the individual to ensure they are appropriately trained to care for a research patient experiencing hypoglycaemia.

5. Causes of Hypoglycaemia

- Delaying or skipping a meal or snack.
- Eating too little carbohydrate food at a meal.
- Participating in more exercise than usual you can have a delayed hypo several hours after exercise.
- Taking too much diabetes medication, especially insulin or sulphonylureas.
- Drinking alcohol.
- Hot weather.
- A change in the insulin injection site e.g., from an area of lipohypertropy to normal skin.
- Stress or illness.

Patients suffering from hypoglycaemia may exhibit or present with any or all of the following symptoms –

- Sweating
- Palpitations
- Shaking
- Hunger
- Paleness
- Confusion
- Drowsiness
- Odd behaviour
- Speech Difficulty
- In coordination
- Headache
- Nausea
- Convulsions
- Coma

6. Procedure

Provide a Hypo box that should be kept in an easily accessible place in your clinical area and all staff must be aware of its location.

Examples of 15-20g quick acting carbohydrates, which should be given, which will raise the blood sugar level quickly:

- 150-200ml pure fruit juice or
- 90-120ml of original Lucozade or
- 5-7 Dextrosol tablets (or 4-5 Glucotabs) or
- 150mls of ordinary coke/lemonade (half a glass)

Examples of slow acting carbohydrate which should be given to prevent the blood sugar level falling again:

- Two digestive biscuits or
- One slice bread/toast or
- 200-300ml glass of milk or
- Normal meal if due (must contain carbohydrate)

The nurse/ delegated person or patients should not omit their insulin injection if due but a dose review may be required.

Mild hypo- the patient is able to take corrective action

- Check the patient's blood glucose level.
- If the blood sugar is below 4mmol/l, administer some quick acting carbohydrate followed by some slow acting carbohydrate.
- Test the blood sugar again in 5 minutes after administrating the quick acting carbohydrate and if required take more quick acting carbohydrate again

The nurse/delegated person should document the event in patient notes and ensure the patient carries out regular capillary blood glucose monitoring.

Patients who are conscious but confused, disorientated, unable to cooperate, aggressive but are able to swallow will require assistance to treat their hypo.

- Check the patient's blood glucose level.
- If the blood sugar is below 4mmol/l and the patient is able to take action himself or herself provide the patient with some quick acting carbohydrate followed by some slow acting carbohydrate.
- If the patient is unable to administer the quick acting carbohydrate themselves but are conscious and able to swallow but or uncooperative/confused then you will need to help the patient.
- Insert 1.5-2 tubes of GlucoGel/Dextrogel squeezed into the mouth between the teeth and gums, this should only be used on people who are conscious not unconscious.
- Test the blood sugar again 5 minutes after administering the quick acting carbohydrate and if required take more quick acting carbohydrate again.
- Once the patient has recovered and is able to swallow, provide them with long acting carbohydrate.

Patients who are unconscious and /or having seizures and/ or very aggressive will always need help.

The following 3 options of treatment are appropriate

- Ask for Medical help.
- Place the patient in the recovery position if appropriate.
- Check the patient's blood glucose level.
- Give GLUCAGEN[™] or Glucagon Img IM. Glugacon may take up to 15 minutes to work.
- Glucagon may cause nausea afterwards.
- The effect of glucagon only lasts for a short time.
- Once the patient has recovered and is able to swallow, provide them with some long acting carbohydrate.

Or

- If IV access is available, give Intravenous glucose 20% preferable 75-80ml over 10-15 minutes.
- Repeat capillary blood glucose measurement 10 minutes later if still less than 4.0mmol/L repeat.

Or

- If IV access available give 150-160 ml of 10 glucose over 10-15 minutes.
- Repeat capillary blood glucose measurement 10 minutes later if still less than 4.0mmol/L repeat.
- Once the patient has recovered and is able to swallow, provide them with some long acting carbohydrate.
- If the patient has been given glucagon they will require a larger portion of long acting carbohydrate to replenish glycogen stores (double the suggested amount above).

Equipment

Contents for a Hypo box

Guidelines for staff to follow 1x 200 ml carton fruit juice or 120 ml Lucozade original 1x packet of dextrose tablets 1x mini pack of biscuits Bottle of Lucozade Glucogel / Hypostop Butterfly Cannula Dressing IV Glucose 20% Blood glucose meter and strips – meter should be calibrated and checked regularly for accuracy. Ketone meter and strips – meter should be calibrated and checked regularly for accuracy.

Glucagon requires to be kept in the fridge

Hypo Box contents should be checked regularly to ensure it is complete and in date. It is the responsibility of the member of staff who uses any contents to replenish them after use.