



The ABCD Nationwide Degludec Audit - Objectives

Using modern technologies to facilitate easy gathering of anonymised data, ABCD is setting up a nationwide audit of insulin degludec (Tresiba) in real clinical use in the UK. The aim will be to ascertain whether the experience in real clinical use matches the data from phase 3 clinical trials and also to depict which patients are prescribed insulin degludec and what the clinical outcomes are. Clinicians using insulin degludec will be invited to submit the data that they routinely collect as they monitor the progress of their patients (HbA1c, hypoglycaemia, etc) to the nationwide audit. An IT tool has been developed to make this process as easy and user friendly as possible. It will also facilitate easy analysis of locally collected data by the local clinicians. ABCD hopes to gain insight into both the safety and efficacy of insulin degludec. ABCD hopes that the data from the nationwide audit will inform future practice and guidelines.

ABCD aims to gather the following endpoints:

- **Diabetes type** (type 1, type 2, other)
- **Patient characteristics** at initiation of insulin degludec (age, sex, ethnicity, duration of diabetes, HbA1c, weight, BMI, BP, lipids, ALT)
- **Rationale for starting insulin degludec** (problems with hypoglycaemia, poor compliance - e.g. need flexible injection timing, needs high dose insulin, needs OD basal insulin, as an alternative when considering going onto pump therapy, to fit in with variably timed visit by third party to administer (eg district nurse, relative), intrasubject variability of glucoses with current basal insulin, other)
- **Current diabetes medication** (types and doses, including insulin)
- **Issues if already on insulin** (injection sites problems, at what glucose level does the patient know they are going low)
- Assessment of **awareness of hypoglycaemia** (Gold Score)
- Current **frequency of episodes of hypoglycaemia** both minor (self-treated), severe (3rd party intervention) and nocturnal (either minor or severe - between midnight to 6.00am)
- **Detail regarding each episode of severe hypoglycaemia** (blood glucose value (if recorded), symptoms (remembered by patient, reported by 3rd party helper: confused but conscious, semi-conscious (earlystupor), unconscious). How it was treated (family

member/friend, ambulance call out, hospitalisation, required oral glucose, required IM Glucagon, required IV glucose)

- **Information at initiation of degludec** (start dose, who will administer degludec? [patient, relative, health professional, other], proposed time of degludec administration [morning, lunchtime, afternoon, evening/bedtime, variable], change of other diabetes medication [including change to previous insulin dose])

At follow up:

- **How long since starting degludec** – months
- **If still taking insulin degludec**, current dose
- **If not taking degludec**, when was it stopped?; why it stopped?
- **Current patient characteristics** (HbA1c, weight, BMI, BP, lipids, ALT)
- **Who administers degludec?** (patient, relative, health professional, other)
- **When is degludec administered?** (morning, lunchtime, afternoon, evening/bedtime, variable)
- **Current diabetes medications** (types and doses, including insulin)
- Current **frequency of episodes of hypoglycaemia** both minor (self-treated), severe (3rd party intervention) and nocturnal (either minor or severe - between midnight to 6.00am)
- **Detail regarding each episode of severe hypoglycaemia** (blood glucose value (if recorded), symptoms (remembered by patient, reported by 3rd party helper: confused but conscious, semi-conscious (early stupor), unconscious). How it was treated (family member/friend, ambulance call out, hospitalisation, required oral glucose, required IM Glucagon, required IV glucose)
- **Injection sites problems**
- **Any new adverse events/medical conditions, including pregnancies**