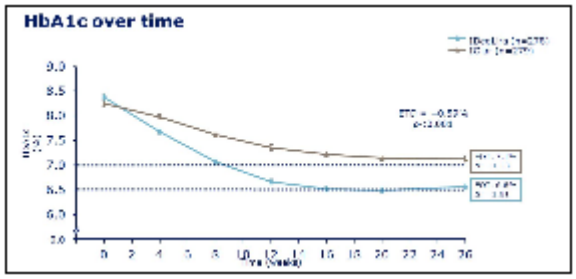

Association of British Clinical Diabetologists

The ABCD Nationwide IDegLira Audit - Objectives

Using modern technologies to facilitate easy gathering of anonymised data, ABCD is setting up a nationwide audit of IDegLira (Xultophy) 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 IDegLira and what the clinical outcomes are. Clinicians using IDegLira will be invited to submit the data that they routinely collect as they monitor the progress of their patients (HbA1c, weight, 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 IDegLira . ABCD hopes that the data from the nationwide audit will inform future practice and guidelines.

ABCD aims to gather the following endpoints:

Primary endpoint

The primary endpoint will be change in HbA1c from baseline to 6 months after IdegLira initiation.

“Baseline values” are defined as the most recent values during the 6-month period prior to first prescription of IdegLira. As the interval of patients visits to their clinicians will vary, endpoint data will be collected with a window of ± 45 days around the 3, 6, 9 and 12 month time points.

The primary endpoint will be assessed for the whole patient group and separately in specific subgroups according to their last antidiabetic treatments before initiating IdegLira. Classification of prior therapy will be based on classes of glucose-lowering drugs.

Other outcomes

Glycaemic outcomes at other time points:

Change in HbA1c from baseline to after 3, 9 and 12 months of IdegLira treatment.*

Other diabetes-related effectiveness parameters:

Percentage of responders for HbA1c after 3, 6, 9 and 12 months of IdegLira treatment

HbA1c < 7% (53 mmol/mol)*

HbA1c < 7% (53 mmol/mol) with no weight gain and no hypoglycaemic episodes*

Hypoglycaemia

Proportion of patients with at least one hypoglycaemic episode by category (overall, severe, non-severe, nocturnal) during the month prior to the first return visit after IdegLira initiation, compared to the 1 month period before first IdegLira prescription.

Number of hypoglycaemic episodes by category (overall, severe, non-severe, nocturnal) during the month prior to the first visit after IdegLira initiation, compared to the 1 month period before first IdegLira prescription.

Study variables

- Duration of diabetes (year) (baseline only), HbA1C, Weight, Height, Blood pressure, Creatinine, Total Cholesterol, HDL, LDL Cholesterol, Triglycerides, Alanine aminotransferase (ALT).
- Has the patient ever had pancreatitis (defined by Atlanta criteria)?
- Has this patient had bariatric surgery?

- **Rationale for starting IDegLira**
    - Achieving glycaemic control
    - Problems with hypoglycaemia on current treatment
    - Stop or reduce weight gain
    - Poor compliance on current treatment
    - Preferred once daily combination regimen instead of free combination
    - Intra-subject variability of glucoses with current basal insulin
    - To fit in with variably timed visit by third party to administer (eg district nurse, relative...)
    - Other (please specify):
- **Antidiabetic treatment before initiating IdegLira**
    - Types, class and doses, (including insulin)
    - Other antidiabetic medications Or medications which could affect glycaemic control
    - Anti-obesity medication

- **Antidiabetic treatment after initiating IdegLira**
    - Types, class and doses, (including insulin)

    - Other antidiabetic medications Or medications which could affect glycaemic control
    - Anti-obesity medication
- **Initiation of IdegLira**
    - *Date, dose, time*

- **Status on IDeglira treatment**

    - Ongoing? If stopped- reason for stopping
    - Any (GI) side effects reported?

- **Hypoglycaemic history**
    - Total number of hypoglycaemic **events in the last month**:
    - Minor (Defined as self-treated symptomatic hypoglycaemia as declared by patient - even in the absence of blood glucose measurement)
    - Severe (3rd party intervention - defined as patient could not have self-treated. Excludes cases where a patient could have self-treated but a kind person helped)defined as patient could not have self-treated:
    - Nocturnal (Either minor or severe, 00:00 to 06:00):

- **Any new adverse events/medical conditions, including pregnancies**