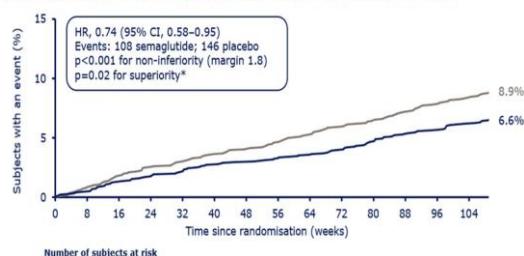


Primary outcome

FIRST OCCURRENCE OF CV DEATH, NON-FATAL MI OR NON-FATAL STROKE



The ABCD Nationwide Semaglutide Audit - Objectives

ABCD is setting up a nationwide audit of semaglutide (Ozempic) 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. Clinicians using semaglutide will be invited to submit the data that they routinely collect as they monitor the progress of their patients (HbA1c, weight etc) to the nationwide audit. Based on technologies used in previous such audits, a secure, on-line, encrypted, IT tool is being 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 semaglutide. ABCD hopes that the data from the nationwide audit will inform future practice and guidelines.

From the data submitted in the audit ABCD hopes it might be able to quantify and analyse in detail:

- How much **weight loss** occurs with semaglutide in real clinical use. Is weight loss durable over time?
- How much **HbA1c reduction** occurs with semaglutide in real clinical use. Is this reduction durable over time in the real world?
- What percentage of patients achieve both **HbA1c reduction** and **weight loss** with semaglutide as opposed to just one or neither of these parameters.
- In our liraglutide audit the efficacy appeared to be less with **duration of diabetes** – does this also apply to semaglutide?
- What is the real world experience of **progression to insulin treatment** in patients treated with semaglutide ?
- What is the impact on **lipids** of semaglutide in real clinical use
- What is the impact on alanine aminotransferase (ALT) of semaglutide – through weight loss and impact on lipids might semaglutide improve non-alcoholic fatty liver disease (**NAFLD**).
- Who are the patients **who respond** especially well to semaglutide in real clinical use – does it relate to initial HbA1c, weight, body mass index, duration of diabetes, initial age or sex, ethnicity or particular other medications being used etc. Is it possible to predict the patients who are more likely to respond to semaglutide .
- Similarly, who are the patients **who don't respond** to semaglutide ?
- What percentage of patients using semaglutide have a **history of cardiovascular disease**? How much cardiovascular benefit are we likely bringing to our patients if we

assume the benefits found in the SUSTAIN6 trial? How does that benefit compare with that predicted by the UKPDS risk engine?

- What are the **side effects**? Semaglutide seems to be more effective than previous GLP1 receptor agonists – are the side effects worse as a result of a more potent medication?
- If there are **safety issues** with semaglutide which may come out in due course, we hope to get some forewarning of these now through pooling the national experience.
- To what extent does semaglutide allow avoidance of insulin and continuation in their jobs for **professional drivers**, or regaining of their jobs for such workers who have lost them through insulin?
- What is the size of the problem of **hypoglycaemia** with semaglutide and insulin, or semaglutide and sulphonylureas. Is there a problem of worsening hyperglycaemia if insulin is stopped and semaglutide started? Are there guidelines that can be deduced from the nationwide experience with regard to how to add semaglutide to insulin and how to add semaglutide to sulphonylureas without inducing hypoglycaemia or hyperglycaemia.
- What percentage of patients **cannot tolerate semaglutide** in real clinical use?
- Is the clinical efficacy of semaglutide sustained in real clinical use? Does the weight loss continue with time or does it plateau off?
- Are there benefits, or otherwise, in combining other medications such as **SGLT2 inhibitors** and/or **thiazolidinediones** and semaglutide

ABCD, November 2018