

September 2009:

The ABCD Nationwide Liraglutide Audit - Objectives

Using computer networking and modern technologies to facilitate easy gathering of anonymised data, ABCD is setting up a nationwide prospective audit of liraglutide 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 liraglutide 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. An IT tool will be 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 ascertain both safety and efficacy. ABCD hopes that the data from the nationwide audit will inform future practice and ABCD 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 Liraglutide in real clinical use. Is weight loss durable over time?
- How much HbA1c reduction occurs with Liraglutide in real clinical use. Is this reduction durable over time in the real world?
- What is the real world experience of progression to insulin treatment in patients treated with liraglutide?
- What is the impact on lipids of Liraglutide in real clinical use
- What is the impact on alanine aminotransferase (ALT) of Liraglutide – through weight loss and impact on lipids might Liraglutide improve non alcoholic fatty liver disease (NAFLD).
- Who are the patients who respond especially well to Liraglutide in real clinical use – does it relate to initial HbA1c, weight, body mass index, duration of diabetes, initial age or sex, or particular other medications being used etc. Is it possible to predict the patients who are more likely to respond to Liraglutide.
- Similarly, who are the patients who don't respond to Liraglutide?
- Currently Liraglutide usage with insulin is off license but, as with exenatide, it is likely that some diabetologists may try it with insulin, in certain particular difficult clinical situations, where such a usage seems to be best for the patient. The nationwide audit affords an opportunity to pool experience of usage of Liraglutide with insulin across the nation, find out how useful this approach is, the extent to which control is improved, insulin dose is reduced or insulin is even stopped. The data may help bring forward the licensing of usage of Liraglutide with insulin, if the combination does prove to be a good one
- What are the side effects? The possibility of thyroid problems and pancreatitis have both been considered in relation to Liraglutide usage but neither seem to have come through as causes for concern in the phase 3 clinical trials. Nevertheless worries continue in the minds of many clinicians who will feel reassured that there is a robust reporting system for adverse events in place through the audit. The audit provides a vehicle for further reassurance with regard to these side effects to compliment the phase 3 trials. Are there any important side effects that have not yet been identified?
- If there are safety issues with Liraglutide 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 Liraglutide 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 Liraglutide and insulin, or Liraglutide and sulphonylureas. Is there a problem of worsening hyperglycaemia if insulin is stopped and Liraglutide started?
- Are there guidelines that can be deduced from the nationwide experience with regard to how to add Liraglutide to insulin and how to add Liraglutide to sulphonylureas without inducing hypoglycaemia or hyperglycaemia.
- What percentage of patients cannot tolerate Liraglutide in real clinical use?
- Is the clinical efficacy of Liraglutide sustained in real clinical use? Does the weight loss continue with time or does it plateau off?
- Are there benefits, or otherwise, in combining thiazolidinediones and Liraglutide
- Could we, from the data, calculate the potential benefit in terms of predicting cardiovascular event reduction on the as yet unvalidated assumption that the reduction in risk factors is translated into prevention of cardiovascular events?