COMPARISON OF TWO METHODS FOR MEASURING HAEMOGLOBIN LEVEL IN A CLINICAL TRIAL SETTING.

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Patients with chronic obstructive pulmonary disease were screened, using both a near to patient (NTP) assay for haemoglobin (Hb) and the automated laboratory based Hb assay for participation in a clinical trial of an erythrocyte stimulating factor. Our aim was to assess reproducibility of the NTP assay with the gold standard laboratory based Hb assay.

Methods: A random sample of 57 adults (20-70yrs) was recruited. A venous blood sample was collected by venipuncture and analysed by the standard laboratory based Cell-Dyn 4000 method. A finger prick sample was also collected and assayed by the HemoCue® photometer (NTP assay). Reproducibility was determined by intra-class correlation co-efficient.

Results: The mean (95%CI) for Hb measured by photometer was 13.99g/l (13.65-14.33) and the mean measured by automated method was 14.24g/l (13.92-14.56). The intra-class correlation co-efficient between the two methods was 0.80.

Conclusions: We found that the HemoCue® and Cell-Dyn 4000 methods produced reproducible results. The importance of accuracy in a clinical trial when a measurement such as Hb is used as inclusion criteria can not be underestimated. The NTP test, given its convenience is suitable for screening.

Key Words: Haemoglobin, Hemocue®, Cell-Dyn 4000, reproducibility.