Trial title	Sitagliptin vs sulphonylurea based treatments in Muslim patients with Type 2 diabetes during Ramadan
R&D PIN	R00209
EudraCT reference	2008-002607-12
REC Reference	08/H1005/46
Sponsor	Manchester University NHS Foundation Trust
Chief Investigator	Professor Rayaz-A Malik

The above referenced open label, phase IV Clinical Trial of an Investigational Medicinal Product (CTIMP) was conducted at Central Manchester and Manchester Children's Hospital NHS Trust (now known as Manchester University NHS Foundation Trust) from 13/08/2008 to 23/04/2011. The trial originally aimed to recruit 200 Muslim men and women with Type 2 diabetes who intend to fast during the month of Ramadan.

The primary objective of the study was to assess the occurrence of hypoglycemia on sitagliptin vs. sulphonylurea based treatments in Muslim patients with type 2 diabetes fasting during Ramadan. The patients recorded hypoglycaemic episodes in a self–monitoring diary together with blood glucose values as measured by finger prick testing.

The secondary objectives were evaluation of changes in:

- Body weight
- Fasting blood sugar (FBS)
- Glycosylated haemoglobin (HbA1c)
- Triglycerides (TG)
- Total cholesterol (TC)
- Low-density lipoprotein-cholesterol (LDL-C)
- High density lipoprotein-cholesterol (HDL-C)

The trial was conducted at the Wellcome Trust Clinical Research Facility at MFT and recruitment was extended to three other sites in 2010 (Brent Community Services NHS Brent, University Hospital Birmingham, Royal Preston Hospital). 20 participants were recruited to the trial and no SAEs were recorded or notified to the Sponsor.

Following review by the sponsor in December 2009, an amendment was submitted to the ethics committee and the MHRA to include additional sites as recruitment had been poor. However the nominated sites could not participate and the recruitment window leading up to Ramadan 2010 was missed. It was concluded that the study would be unlikely to complete as there has been difficulty recruiting participants with only 20 of the intended 150 patients being enrolled in three years.

Further, participants had not fully completed the study diaries which were used to monitor hypoglycaemic events (the primary outcome measure) and there was an incomplete data set for those who had participated. Consequently, there was insufficient data to inform the primary research aim and complete the risk benefit assessment of the Investigational Medicinal Product (IMP).

The decision was taken to close the trial on 23/04/2011 and the REC and MHRA were informed. No participants were still receiving treatment at the time of premature trial termination. Participants were notified of the trial closure and thanked for their participation.

Name: LYNNE WEBSTER Date: 12th Dec 2019

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