NHS
Manchester University
NHS Foundation Trust

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| **Trial title** | Randomised Controlled Trial of Lapatinib (A Her1/2 Tyrosine Kinase Inhibitor) on Epithelial Proliferation and Apoptosis in Ductal Cancer in Situ |
| **R&D PIN** | 2006SG005 |
| **EudraCT reference** | 2006-006619-64 |
| **Sponsor(s)** | Manchester University NHS Foundation Trust |
| **Chief Investigator** | Professor Nigel Bundred |

The above Clinical Trial of an Investigational Medicinal Product (CTIMP) was conducted at University Hospital of South Manchester (now known as Manchester University NHS Foundation Trust) from 18/09/2007 to 18/09/2009. The aim of the trial was to determine the short term anti-proliferative effect and apoptosis inducing effect of Lapatinib, a Her1/Her2 tyrosine kinase inhibitor on epithelial proliferation (as adjudged by Ki67) and apoptosis in Ductal cancer In Situ of the Breast..

The secondary objectives were:

1. To determine the effect of preoperative Lapatinib compared with placebo on apoptosis, survivin and progesterone receptor staining in histologically diagnosed Her2 positive DCIS.

2. To determine the effect of preoperative Lapatinib on epithelial proliferation, apoptosis, survivin and progesterone receptor expression in normal breast tissue from the surrounding breast around a mastectomy or wide local excision after surgical excision for HER2 positive DCIS.

There were no serious adverse events that occurred in the trial.

The trial was terminated by the sponsor on 18/09/2009 as only 12 of the anticipated 80 participants had been enrolled after 10 months of recruitment. There were difficulties obtaining timely HER2 FISH results leading to slow patient recruitment which then resulted in the IMP supplier (GlaxoSmithKline) withdrawing their support for the trial. As a result, no meaningful data was produced and no publication occurred,

**Name:** Nigel Bundred **Date:** 13/03/2020

**Signature:**