

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Dear Sir/Madam,

RE: BBC premature termination

IRAS ID: 138743

Protocol Title: BBC: Phase II study of neoadjuvant cisplatin and gemcitabine chemotherapy versus upfront surgery in patients with resectable proximal biliary tract cancer

Chief Investigator: Professor Daniel Palmer

Sponsor name and address:

The Clatterbridge Cancer Centre NHS Foundation Trust
Clatterbridge Road
Bebington
Wirral
CH63 4JY

EudraCT Number: 2014-022382-30

The above study (BBC) was registered on EudraCT on 03/06/2014 and obtained MHRA approval from the UK competent authority on 13/03/2015.

The study was abandoned before recruiting any patients. This was due to changes in standard of care and financial shortfalls. The trial never opened to recruitment and no patients were randomised

Change in Standard of Care: A national shift in the Standard of Care and patient management of patient with biliary tract cancers. With the increasing role of immunotherapy for many cancer types, a recent global phase III randomised trial has established the combination of chemotherapy with immunotherapy as the new standard of care for systemic therapy for advanced biliary tract cancer. Thus, in order to retain the relevance of the BBC trial, a significant re-design to incorporate immunotherapy is required.

Shortfalls in the funding required to deliver the project: The project was original costed as small pilot study but as the protocol and set-up of the project has progressed it has become clear the grant will not sufficient to deliver the requirements of a CTIMP with significant patient follow-up.

The trial ended prematurely and the End of Trial Notification was submitted on 29/07/2021 with an end of trial date of 19/07/2022. Due to no patient recruitment no clinical trial report is going to be prepared and uploaded.

If you require any further information and/or documentation, then please do not hesitate to contact us using the details below.

Many thanks,


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19 Jul 2023

Charlotte Rawcliffe
Head of Trial Management
Liverpool Clinical Trials Centre