FINAL STUDY REPORT

Study Title: Effect of anastrozole on arthralgia and the influence of glucosamine sulphate supplementation in postmenopausal women with arthralgia in the IBIS-II breast cancer prevention trial

EudraCT number: 2009-015378-36

Protocol number: ART1

Chief Investigator: Prof. Nicholas Wald

Sponsor: Queen Mary, University of London

List of Principal Investigators and Sites	N/A. The study has not opened recruitment and hence no Principal Investigators/sites to be listed.
Study Start and End Dates	N/A. The study has not opened recruitment. End of trial as per end of trial declaration 30/09/2010.
Study Design	To investigate glucosamine sulphate supplementation in 250 postmenopausal women with arthralgia in the IBIS-II prevention study.
No. of Patients (planned and analysed)	None.
Main inclusion/exclusion criteria	Women with arthralgia.
Investigational Medicinal Product(s) (including comparator, if applicable), mode of administration and batch number(s)	Glucosamine sulphate versus placebo (cross-over design), oral intake.
Duration of Treatment	12 months
Primary and Secondary Objective(s)	To investigate the effect of glucosamine sulphate on arthralgia in postmenopausal women at increased risk of developing breast cancer. To evaluate the effect of arthralgia on function by using a pain questionnaire and by employing functional assessment tests such as the grip test.
Endpoints/ Outcome Measure(s)	The primary endpoint is the presence or absence of arthralgia after 6 months of follow-up. The cross-over design after the initial 6 months of follow-up will be a secondary endpoint.
Statistical Methods	N/A.
Conclusions	Although trialists were very keen to evaluate glucosamine sulphate, the recruitment into the main IBIS-II prevention study will finish in December 2011, and at current recruitment rates it was clear that we will be far below the number required to obtain a meaningful result, even if we were

	able to enter 50% of all UK participants, which would be very optimistic. This was largely due to the long time it has taken to get the trial approved, by local centres and the final agreements with the drug company Rottapharm. As a result the IBIS-II Executive Committee has taken a unanimous decision not to proceed with this study.

Authorised by: _____

Signature: _____

Date: _____