

**Charlene Green**

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**From:** Tom Fairfield  
**Sent:** 06 April 2011 17:46  
**To:** Charlene Green  
**Subject:** Important changes to the STAMPEDE trial - recruitment to arms D and F discontinued  
**Importance:** High  
**Attachments:** STAMPEDE General PIS V7.0.doc; Letter to MHRA & Response describing arm dropping actions.pdf

Dear Colleague

**Re: Important changes to the STAMPEDE trial – recruitment to arms D and F discontinued**

The trial data were reviewed by the Independent Data Monitoring Committee (IDMC) on the 31<sup>st</sup> March. This was the 2<sup>nd</sup> intermediate analysis (end of Activity Stage 2). Following this, the STAMPEDE Trial Steering Committee (TSC) has met today and has decided that we are going to stop recruitment to the celecoxib-containing trial arms, D and F. This change will be with immediate effect meaning that no further patients will be allocated to these arms. The IDMC and TSC would like to stress that this decision is on grounds of lack of sufficient benefit and not safety.

We will be contacting all centres in the next few days with more detailed recommendations concerning the patients already on treatment. It is very important that follow-up continues for all of these patients as per the protocol.

Recruitment to arms A, B, C and E continues unchanged as these passed the pre-specified intermediate hurdle for activity. You can continue to recruit patients without waiting for further information from us.

The possibility of stopping an arm has always been an integral part of the trial's design and is built into the approved protocol. For reference, this is described in detail in section 9 of the protocol and published in the journal *Trials*. Hence this change does not constitute a substantial amendment and can be initiated straight away. This has been confirmed in writing with the MHRA and the main Ethics Committee and documentation to this effect has already been sent to you and is attached for reference. Please also find attached an updated general patient sheet, with information concerning arms D and F removed, which can be given to new patients; the arm-specific information sheets for the other continuing arms are unchanged.

The STAMPEDE trial team will formally amend the trial protocol, patient information sheets and consent forms to reflect this change. We'll send you the updated documents in the coming weeks.

If you have any questions about this change please contact Tom Fairfield (0207 670 4831), or Charlene Green (0207 670 4882).

This constitutes an important milestone for the STAMPEDE trial as it means we have now answered one of the questions posed at the outset of the trial. It also means that the remaining trial arms continue to be asking questions judged relevant by both the IDMC and the TSC. Everyone involved in the trial has been congratulated on the running of the trial so far. Your continued involvement is essential to the ongoing success of the trial and the STAMPEDE trial team would like to thank you for your support.

Yours sincerely

06/04/2011

Nick James            Tom Fairfield  
**Chief Investigator    Trial Manager**

<http://www.trialsjournal.com/content/10/1/39>

**Issues in applying multi-arm multi-stage methodology to a clinical trial in prostate cancer: the MRC STAMPEDE trial**

Sydes MR, Parmar MKB, James ND, Clarke NW, Dearnaley DP, Mason MD, Morgan RC, Sanders K, Royston P