Dr [name]

[address]

Date: [date]

Re: [patient identifier]

Dear Dr [name],

This lady has kindly agreed to participate in the PROMISE trial (A multi-centre randomised placebo-controlled trial of progesterone in spontaneously conceived women with a history of unexplained recurrent miscarriages). The study is funded by the NIHR HTA programme, and has an ethical approval from the West Midlands Research Ethics Committee.

Your patient will be randomised to take either progesterone pessaries (400mg twice daily) or identical placebo, from the time of diagnosis of pregnancy to 12 completed weeks of pregnancy. Since this is a double-blind study, neither the participant, nor the investigators will know which treatment your patient has been allocated to. Your patient has the contact details of the research nurse in case of difficulties.

We do not anticipate that your patient's participation in the study will impact on your care of her, and we will not ask you to carry out any study related investigations or interventions.

This letter is for information only.

If you wish any further details, please feel free to contact either myself or the research nurse for the study [research nurse name and contact details]. A copy of the Participant Information Sheet for the PROMISE trial is enclosed.

Thank you for your support,

Yours sincerely,

Dr Arri Coomarasamy, MBChB, MD, MRCOG

Trial manager for the PROMISE study

Consultant Gynaecologist and Subspecialist in Reproductive Medicine

University of Birmingham, UK

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