PROMISE: first-trimester progesterone therapy in women with a history of unexplained recurrent miscarriages – a randomised, double-blind, placebo-controlled, international multicentre trial and economic evaluation

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Declared competing interests of authors: Annemieke Hoek declares research awards from Merck Sharp & Dohme, Ferring B.V. and the Netherlands Organisation for Health Research and Development (ZonMW), and personal fees from Merck Sharp & Dohme, all unrelated to the PROMISE trial.
Plain English summary

The PROMISE trial and economic evaluation
Health Technology Assessment 2016; Vol. 20: No. 41
DOI: 10.3310/hta20410

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Plain English summary

Progesterone is a natural hormone that is essential to maintain a healthy pregnancy, and previous research has suggested an association between lower levels of progesterone and higher rates of miscarriage. This trial was undertaken to test whether or not progesterone given to pregnant women with a history of repeated (three or more, consecutive or non-consecutive) unexplained early pregnancy losses would increase the number of pregnancies leading to live births after at least 24 weeks of gestation, when compared with placebo (a dummy drug). A pregnancy loss is considered to be unexplained if conditions known to increase the risk of miscarriage are absent.

The treatment that each participant in the study received was decided at random by a computer; one group received progesterone (400 mg twice daily as vaginal capsules) and the other group received placebo with an identical appearance, from soon after a positive urinary pregnancy test, and no later than 6 weeks of pregnancy, until 12 completed weeks of pregnancy (or earlier if the pregnancy ended before 12 weeks).

In total, 836 women received the treatment. Altogether, 533 women experienced a live birth after at least 24 weeks of pregnancy. The live birth rate in the progesterone group was 65.8%, compared with 63.3% in the placebo group (women who took the dummy treatment). The difference between these live birth rates is not statistically significant, which suggests that progesterone therapy in the first trimester is of no benefit for women with unexplained repeated pregnancy loss.
Health Technology Assessment

ISSN 1366-5278 (Print)
ISSN 2046-4924 (Online)
Impact factor: 5.027

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 08/38/01. The contractual start date was in October 2009. The draft report began editorial review in January 2015 and was accepted for publication in August 2015. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

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