

Dr Jane Daniels

Senior Research Fellow

Reproduction, Genes and Development

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About

Jane Daniels is the Deputy Director of the **Birmingham Clinical Trials Unit** (<http://www.birmingham.ac.uk/bctu>), portfolio lead for Women's Health clinical trials and senior research fellow in obstetrics and gynaecology. Jane's current research interests include the diagnosis and treatment of chronic pelvic pain and heavy menstrual bleeding.

Qualifications

- PhD Medicine, 2013. University of Amsterdam
- MSc Health Technology Assessment, 200. University of Birmingham
- MMedSci (Research) Clinical Chemistry, 1996. University of Birmingham
- BSc (Hons) Medical Biochemistry, 1992. University of Amsterdam

Biography

Graduating from the University of Birmingham in Medical Biochemistry, Jane's early career was in molecular biology: first in allergology, then in relation to infectious diseases. She left the laboratory in 1998 and became a trial coordinator in the newly created Birmingham Clinical Trials Unit (BCTU). The first trial she coordinated was LUNA, which signalled the start of this ongoing collaboration with Professor Khalid Khan, now at Barts and the London Medical School. At that time, she was also intrinsically involved in the development of the "advice and support" function of the BCTU and collaborated with investigators from many disciplines in developing therapeutic trials in a wide range of conditions, including physiotherapy, psychiatry and neurology. Jane was the trial coordinator for the MRC funded randomised controlled trial of surgery for Parkinson's disease between 2000- 2006.

In the past seven years, Jane has built up a portfolio of research in women's health which currently includes five open randomised controlled trials, two recruiting primary test accuracy studies and three trials in follow-up and analysis, managing a team of 10 trial management staff. She represents the BCTU on several University committees, including the Birmingham Centre for Clinical Trials Executive and Clinical Trials Oversight Committee. Throughout 2011, Jane was the Acting Director for BCTU and remains deputy to Professor Jon Deeks, who took up the role of Director in January 2012.

Teaching

- MPH (Health Technology Assessment)
- MBChB personal mentor

Jane contributes to BCTU's tri-annual Research Methods Course (CPD approved), and gives lectures on systematic reviews, critical appraisal and trial management as part of this course.

Research

Research themes

Evaluation of diagnostic and screening tests, randomised controlled trials of medical and surgical treatments, systematic reviews and meta-analysis, obstetrics, gynaecology and neonatology.

Research Activity

Jane has established the Birmingham Clinical Trials Unit as the one of the leading centres in the UK for clinical trials in obstetrics and gynaecology

Jane's research has immediate impact. The **LUNA** (<http://www.luna.bham.ac.uk/>) Trial showed that among women with chronic pelvic pain, LUNA did not result in improvements in pain, dysmenorrhea, dyspareunia, or quality of life compared with laparoscopy without pelvic denervation. This was published in JAMA in 2009 and has led to the procedure being abandoned across the UK and Europe.

Randomised Controlled Trials

Within the BCTU's women's health portfolio, there are currently three recruiting studies, three where recruitment has finished and women and babies are being followed up.

FEMME (<http://www.femme.bham.ac.uk/>) is a randomised trial comparing myomectomy with uterine artery embolisation in women with bothersome fibroid, looking mainly at the impact of the treatment on quality but also at fertility and pregnancy outcome.

Women with early onset pre-eclampsia are often faced with a terrible dilemma – risk their condition deteriorating or have their baby delivered prematurely. In the **StAmP** (<http://www.stamp.bham.ac.uk/>) trial, such women are randomised between a daily dose of a statin or a placebo, to see if this has an impact on biomarkers in the blood known to cause pre-eclampsia and of course, to see if the statin prolongs the pregnancy.

It has been shown that having anti-thyroid antibodies increases the risk of miscarriage and pre-term birth, and creates a relative deficiency of the hormone thyroxine. What is not clear is whether giving thyroxine before and during pregnancy improves outcomes. The **TABLET** (<http://www.tablet.bham.ac.uk/>) trial is addressing this by recruiting 900 women with anti-thyroid antibodies to receive thyroxine or placebo.

ECLIPSE (<http://www.eclipse.bham.ac.uk/>) recruited 580 women and has demonstrated the superior cost and clinical effectiveness of the Mirena® coil compared to oral treatments for heavy menstrual bleeding. This was published in the New England Journal of Medicine in early 2013.

PLUTO (<http://www.pluto.bham.ac.uk/>) aimed to determine if intrauterine vesico-amniotic shunting for fetal bladder outflow obstruction, compared to conservative, non-interventional care improves perinatal and neonatal mortality and renal function. The trial is only the second RCT in fetal medicine and being a rare condition had difficulties in recruiting mothers. The trial was closed with 30 women recruited and the data are being analysed.

OPT (<http://www.opt.bham.ac.uk/>) is an equivalence trial that will determine reliably whether out-patient polyp removal under local anaesthetic is clinically as effective as in-patient surgery for women with uterine polyps, and to determine the relative cost-effectiveness of each strategy. This recruited its target of 480 women in July 2011. The results will be published in 2013.

Screening and Diagnostic Test Accuracy Studies

There are three recruiting studies in the BCTU women's health portfolio, with two studies having closed and reported.

The **GBS** (<http://www.gbs.bham.ac.uk/>) Study concluded intrapartum PCR screening is a more accurate predictor of maternal and neonatal GBS colonisation than is OIA or risk factor-based screening, and whilst acceptable to women, is not cost-effective.

The **PulseOx** (<http://www.pulseox.bham.ac.uk/>) study recruited over 20,000 babies from across the West Midlands. The conclusion was that PO is a simple, safe, feasible test which is acceptable to parents and staff and adds value to existing screening. It is likely to identify cases of critical CHD which would otherwise go undetected. It is also likely to be cost-effective given current acceptable thresholds. We await the decision of the NHS Screening Committee on whether this will be implemented nationally.

Systematic Reviews and Meta-Analysis

Jane has completed two individual patient data (IPD) meta-analyses. The **LUNA IPD MA** confirmed the results of the LUNA trial and was the first IPD MA published in Human Reproduction Update. The **Heavy Menstrual Bleeding IPD MA**, in collaboration with Aberdeen University, was initiated as a RCT but was considered impossible to run. This review also involved economic modelling and surprisingly showed hysterectomy is more cost effective than modern endometrial ablation techniques. Jane is author of several systematic reviews of published data in various gynaecological conditions.

Maternal mortality and global health

With Prof Khan, the academic department of O&G, health economics and BCTU was designated a WHO Collaborating Centre for Research Synthesis in Reproductive Health. This prestigious award led to a collaborative project with the WHO in estimated the global distribution of the causes of maternal mortality. The data arising from this review will directly influence WHO, governmental and NGO policies addressing the maternal mortality targets of the Millennium Development Goal 5.

Jane is further developing international collaborations through involvement in the EBM Connect Project. This is a Marie Curie "People" funding programme which will fund exchange visits with partners in the Netherlands, Spain, Argentina, China, Canada and with the WHO. Jane is working with partners on enhancing the quality of systematic reviews and guidelines, delivering workshops to educate researchers in the partner countries on research synthesis methodologies.

Other activities

- Associate Member of the HTA Clinical Trials Board
- Deputy Chair of RCOG Menstrual Disorders Clinical Studies Group
- Affiliate of Royal College of Obstetricians and Gynaecologists
- Member of the European Society of Gynaecological Endoscopy

Publications

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