

## Clinical trial confirms safety of inducing mothers aged 35 and over to avoid stillbirth and other complications

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A large clinical trial to assess the benefits or otherwise of inducing labour in pregnant women of 35 years or older has found there was no significant effect on the rate of caesarean sections and no adverse effect on the mother and newborn baby.

The large, randomised, controlled study was carried out by researchers in Nottingham with the help of around 600 older first time mothers from all over the UK. It was designed to explore whether induction is an effective obstetric intervention that is currently being underused.

The results of the NIHR-funded trial was carried out by a research team led by The University of Nottingham and Nottingham University Hospitals Trust and is being published in the *New England Journal of Medicine*.

The average age of women giving birth in industrialised countries has been increasing for the past 30 years. In the 10 years until 2006, births to women 35 years or older in the UK went from 12 per cent to 20 per cent of all deliveries. The risks of stillbirth, pre-eclampsia, pregnancy diabetes and problems with the placenta are all higher in pregnant women aged 35 or over and they are more likely to deliver premature and underweight babies.

These women are also more likely to have problems in labour with 38



per cent ending up with caesarean sections, rising to 50 per cent of women over 40 years of age having their first baby.

The Nottingham trial randomly assigned pregnant women who volunteered to take part either to labour induction at 39 weeks or to 'expectant care'—waiting until the spontaneous onset of labour or the development of a medical problem that warranted intervention. Induction of labour was achieved by the insertion of a pessary or an intravenous hormone drip.

Of the 619 women who took part there were no significant differences between the two groups in how many ended up having caesarean sections or in the percentage of women who had a vaginal delivery with forceps or vacuum-assisted delivery.

There were no maternal or infant deaths and no significant differences between the groups in the women's experience of delivery or in the frequency of adverse outcomes for mother and baby.

Professor of Obstetrics and Gynaecology at The University of Nottingham, Jim Thornton, said: "We were fairly surprised by our main result in that overall there was no significant effect on the rate of <u>caesarean section</u> in the group of mums who were induced at 39 weeks. Our trial was not set up to test induction as a way of avoiding stillbirth but it does prove the safety of performing a much larger trial to test this further.

"Some people say why not just induce everyone at 39 weeks and prevent some stillbirths. Others say that would medicalise many normal pregnancies, increase intervention rates and may have long term unintended harms. Ours is the first clinical trial to provide some hard evidence to help decision-making among doctors and older first-time mothers-to-be. The results support the 'induce more women' advocates,



although there are still reasons for caution."

One of the <u>women</u> who took part in the trial said: "Having chosen to start a family later in life, we were very much aware of the increased risk of complications, so when asked to take part in the trial, given the reasons for the research it was an easy decision. I was completely supported by the trial team throughout my pregnancy, which was very reassuring."

Lay member of the research team, Chris Wild smith, who lost a baby through stillbirth said: "I'm really encouraged by the results of the study, especially as it has covered such a difficult subject and area that isn't easy to suggest studies or research without creating more angst or worry among future parents. I really hope the work can generate more discussion to the clinical approach and how to address risk groups. I do hope for all our stillborn children that the evidence will avoid more families going through the traumatic pain and hurt that we endured."

The Randomised Trial of Labour Induction in Women 35 Years of Age or Older was carried out by the Divisions of Obstetrics and Gynaecology at The University of Nottingham and Nottingham University Hospitals NHS Trust; Nottingham Clinical Trials Unit, Stillbirth and Neonatal Death Charity, London; and the Department of Obstetrics and Gynaecology and National Institute for Health Research Biomedical Research Centre, Cambridge University.

## Provided by University of Nottingham

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