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## **Title**

Cell Salvage during Caesarean Section: A Randomised Controlled Trial (The SALVO Trial)

## **Objective**

Excessive haemorrhage at caesarean section requires the use of donor (allogeneic) blood transfusion. The SALVO trial assessed whether the routine use of cell salvage during caesarean section can reduce the need for donor blood transfusion.

## **Methods**

We conducted a randomised controlled trial (26 UK obstetric units; June 2013 through April 2016) of routine cell salvage use (intervention) vs. current standard of care without routine salvage use (control) in caesarean section among women at risk of haemorrhage. We used multivariable models, adjusting for stratification variables and prognostic factors identified *a priori*, to compare rates of donor blood transfusion (primary outcome) and fetomaternal haemorrhage  $\geq 2$ ml in RhD-negative women with RhD-positive baby (one of the secondary outcomes) between groups.

## **Results**

Of 3028 women randomised, 2990 were analysed (after exclusions for vaginal delivery or hospital transfer after randomisation). Of 1498 assigned to intervention, 95.6% had cell salvage deployed (50.8% had salvaged blood returned; mean 259.9 ml) vs. 3.9% of 1492 assigned to control. Donor blood transfusion rates were lower in the intervention group than in control (2.5% vs. 3.5%, adjusted odds ratio [OR] 0.65, 95% confidence interval [CI] 0.42 to 1.01). No case of amniotic fluid embolism was observed. Fetomaternal haemorrhage was higher with intervention vs. control (25.6% vs. 10.5%, adjusted OR 5.63, 95% CI 1.43 to 22.14).

**Conclusion:**

There was modest evidence for an effect of routine use of cell salvage during caesarean section on donor blood transfusion. The increased fetomaternal haemorrhage emphasises the need for adherence to guidance on anti-D prophylaxis and for research on risks of alloimmunisation to RhD and other red cell antigens following cell salvage. (Funder: UK National Institute of Health Research Health Technology Assessment programme, ISRCTN66118656)