

Big Baby Eligibility Guidance

Each week we have a lot of eligibility queries, we hope this document can help you to decide if the patient may be eligible.

Inductions for LGA

Many obstetricians are recommending induction for LGA and there is confusion if these women should enter the trial.

If you discuss the trial with the participant before they see the obstetrician, then you can offer them the trial. The obstetrician will then need to sign the essential recruitment document to say they can take part. If the participant is randomised and allocated to standard care and the obstetrician recommends induction – we strongly recommend this is done after 40 weeks gestation.

If you see the participant after the Obstetrician has reviewed the participant and the obstetrician has made the following plans, please follow the table.

Induction booked (has a date) $\geq 40^{+0}$	Can enter the RCT & cohort
Induction planned for $\geq 40^{+0}$	Can enter the RCT & cohort
Induction booked (has a date) for $< 40^{+0}$	Cannot enter RCT & cohort
Induction planned for $< 40^{+0}$	Please speak to the obstetrician and ask if they would be happy to induce on the due date.

If the woman has opted for caesarean section and is delivered at 39 weeks they can still enter the cohort study.

Inductions for Other Reasons

One of the exclusion criteria is “caesarean section or induction indicated due to health conditions such as cardiac disease or hypertensive disorders”.

If there is a plan to induce the woman before 40^{+0} weeks gestation due to another health condition, then the woman cannot enter the RCT and cohort study.

If there is a plan to induce the woman after and including 40^{+0} weeks gestation then the woman can enter the RCT and cohort study.

The Cohort Study

The cohort study has exactly the same inclusion and exclusion criteria as the RCT. We are interested in outcomes for women where they have chosen their delivery option. I.e. the woman wanted early induction, expectant management or caesarean section. If the obstetrician has booked for the woman to be induced before 40^{+0} weeks gestation these women are not eligible for the cohort study.





Polyhydramnios

Women with polyhydramnios can be included in the RCT and cohort, providing there is no plan to induce her before 40⁺⁰ and the named obstetrician is happy for her to participate.

Glucose tolerance test

If you have a participant who meets all the eligibility criteria, but a glucose tolerance test / blood sugar monitoring has been arranged the participant can still be included in the RCT and cohort study.

If the test finds the woman has GDM and has been randomised the woman does not need to be withdrawn. Any event that happens after randomisation is classified as an outcome and is recorded on the case report form.

Metformin for Polycystic Ovaries

If the woman is taking metformin for polycystic ovaries she can be included in the trial.

If the woman is taking metformin for diabetes she cannot be included in the trial.

Method of induction

We do not specify which method of induction is used. Please follow your local hospital policy and document what was used in the case report form.

IVF

Women with an IVF pregnancy can be included in the RCT and cohort, providing there is no plan to induce her before 40⁺⁰ and the named obstetrician is happy for her to participate.

Previous Caesarean Section

Women with a previous caesarean section can be included in the RCT and cohort, providing the named obstetrician is happy for her to participate.

If you have any more eligibility queries, please contact the trial managers on

024 76 523858

