A randomised controlled trial of iodide supplementation in preterm infants

Results Leaflet

Version 1, 20 April 2017

Clinical Trials Number NCT006380928 REC Ref: 08/S0501/31

We are pleased to be able to tell you that the results of the I2S2 trial of iodine supplementation for preterm infants have now been published. We are contacting you firstly to thank you for having helped us to make this possible by allowing us to include your baby in the trial and secondly, to summarise the results from the trial for you. If you want the results in greater detail they are available at: http://pediatrics.aappublications.org/content/early/2017/04/12/peds.2016-3703.

The reasons for doing the trial

The main aim in doing the trial was to find out whether a daily supplement of iodine could improve the neurodevelopment of preterm infants. Iodine is needed by the body to produce thyroid hormones and thyroid hormones are essential for normal brain development, especially during the early years of life. Many preterm infants are fed parenterally (nutrition that is given directly into a vein) during their stay in hospital. The levels of iodine in the parenteral feeding solutions and in the milks, both formula and breast, may be too low for the needs of premature babies, therefore we designed the trial to find out whether a small iodine supplement would make a difference to thyroid hormones and in turn neurodevelopment.

What we did

Between March 2010 and December 2012 we recruited 1,273 babies born before 31 weeks of gestation from hospitals in Scotland, England, and Northern Ireland. Half of the babies were randomly allocated to receive the iodine solution and half to receive an inactive solution called a placebo that looked exactly the same. Nobody looking after the babies or involved with running the trial knew what any individual baby received and there were no other differences in how the babies were cared for. We collected details about the babies' thyroid hormones and progress during their stay

in hospital. When the children were around two years of age we invited you back and measured your child's development. This was done by a specially trained researcher using a standard developmental test called the 'Bayley Scales'. The Bayley Scales give an idea about three domains (aspects) of child development: their cognitive ability (how well they think), their motor ability (how well they move) and their language ability (how well they speak).

What we found

Neurodevelopmental assessments were undertaken in 498 children who received the iodine solution and 499 children who received the placebo solution. There were no differences in any of the Bayley scale measures between the children who received the placebo and those who received the iodine solutions. The I2S2 trial was large enough for us to be sure that there is no benefit in routinely giving iodine supplements to preterm infants. We are also sure that giving the iodine supplement at 30 mcg/kg/day is associated with no complications.

The results of the I2S2 trial do not support giving iodine supplements routinely to all preterm infants. (This evidence may not apply to the smaller group of preterm infants who are given primarily parenteral nutrition over prolonged periods i.e. several weeks.)

We do trials when we are uncertain whether or not a treatment or supplement is helpful and it is very important that we do not use treatments or supplements that do not help.

Although the I2S2 trial found no benefit in giving routine iodine supplements we have still learned a great deal about thyroid function in preterm infants, and a clear result is very important, either way, ending years of uncertainty.

We are very grateful for your help with this important trial.

The results are available in greater detail at:

http://pediatrics.aappublications.org/content/early/2017/04/12/peds.2016-3703

If you would prefer a paper copy of the results, please write to:

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