Withdrawal of an infant from I2S2 trial solutions after exposure to excess iodine through use of iodinated contrast media or iodinated skin disinfectants

- Exposure to excess iodine may cause transient hypothyroidism.

- If the infant is known to have been exposed to excess iodine (e.g. through iodinated contrast media for visualisation of longlines, cardiac catheterisation, gastrografin meal or enema, or through exposure to iodinated skin disinfectant) the infant should be withdrawn from I2S2 trial solutions immediately.

- TSH and FT4 levels should be measured immediately in your local NHS laboratory and repeated at 10 days following exposure to excess iodine.

- It is recommended that a local consultant paediatric endocrinologist be involved soon after exposure to excess iodine is known, to guide further investigation and treatment if necessary.

- The section of the case report form on withdrawal from I2S2 trial solutions should be completed.

- As the trial analysis is based on intention to treat, the infant should remain in the trial i.e. trial Guthrie cards should be sent, case report forms completed, and the neurodevelopmental assessment done.

- The local principal investigator should inform the parents that withdrawal from I2S2 trial solutions and the recommended investigations/management are very much precautionary measures. I2S2 trial solution (if their infant was in the sodium iodide arm) would have contributed additional microgram amounts of iodine, in contrast to exposure to potentially milligram quantities through contrast media or skin disinfectants.
Guidance Sheet 10: Withdrawal of an infant from I2S2 trial solutions after exposure to excess iodine

**Local Principal Investigator**

- Inform parents that withdrawal of their infant from I2S2 trial solutions and subsequent management/investigations are precautionary measures.
- The I2S2 trial solution of iodide (if in that arm of the trial) is miniscule when compared to the potential amount received via contrast media.

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**Diagram**

- **Known exposure to excess iodine**
  - **YES**
  - **Withdraw infant from I2S2 trial solutions immediately**
    - Principal investigator should refer to paediatric endocrinologist for management
    - Immediately arrange diagnostic tests for hypothyroidism, and repeat tests 10 days after exposure
  - Continue trial Guthrie Card bloods and complete I2S2 case report forms