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FDA: Monitor thyroid in newborns, young children who receive iodine-containing contrast media

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from the Food and Drug Administration

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The Food and Drug Administration (FDA) is advising health care professionals to evaluate thyroid function in pediatric patients 3 years and younger within three weeks of receiving iodine-containing contrast media.

The FDA first alerted the public about cases of hypothyroidism in infants receiving iodine-containing contrast media in 2015. Since then, several studies evaluating this risk have been published.

Those at increased risk of hypothyroidism or a temporary decrease in thyroid hormone levels after receiving iodine-containing contrast media include neonates, particularly those born prematurely or with very low birth weight, and children younger than 3 years who have cardiac conditions or have had other problems requiring care in neonatal or pediatric intensive care units. Pediatric patients with cardiac conditions may be at greatest risk since they often require high doses of contrast during invasive cardiac procedures.

Although these forms of thyroid dysfunction after receiving iodine-containing contrast are uncommon and usually temporary, the conditions should be identified and, when needed, treated early. Hypothyroidism during early life may be harmful for motor, hearing and cognitive development and may require levothyroxine (T4) replacement therapy.

The FDA made this recommendation based on review of 11 published studies that assessed thyroid function in cohorts ranging from 10 to 2,320 children from birth through 3 years who were exposed to iodine-containing contrast media. In these studies, most cases of decreased thyroid hormone levels were temporary and did not require treatment. The reported rate of decreased thyroid hormone levels ranged from 1% to 15% and tended to be higher in newborns, particularly those who were born preterm. The time from iodine-containing contrast media exposure to diagnosis ranged from 8.5 to 138 days, with most occurring within three weeks in some of the publications.

The FDA has approved a new warning to the prescribing information for the entire class of iodinated contrast media injections to describe the risk of hypothyroidism or a temporary decrease in thyroid hormone levels and recommendations for monitoring. The FDA is urging health care professionals to report side effects involving iodine-containing contrast media to the FDA MedWatch program.

The FDA's Office of Pediatric Therapeutics (OPT), Division of Pediatric and Maternal Health (DPMH) and Division of Imaging and Radiation Medicine (DIRM) contributed to this article. OPT resides in the Office of Clinical Policy and Programs in the Office of the Commissioner. DPMH resides in the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine. DIRM resides in the Office of Specialty Medicine. Both DPMH and DIRM reside within the Office of New Drugs in the Center for Drug Evaluation and Research.

Resource

FDA Drug Safety Communication on thyroid monitoring in babies and young children who receive injections of iodine-containing contrast media for medical imaging