

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

Children with underlying conditions and newborns at higher risk

This is an update to the [FDA Drug Safety Communication: FDA advises of rare cases of underactive thyroid in infants given iodine-containing contrast agents for medical imaging](#) issued on November 17, 2015.

3-30-2022 FDA Drug Safety Communication

What safety concern is FDA announcing?

Based on our recent review of published studies, the U.S. Food and Drug Administration (FDA) is recommending that newborns and children through 3 years old have follow-up thyroid monitoring within 3 weeks after receiving injections of contrast media containing iodine, also called “contrast dye,” for X-rays and other medical imaging procedures. Our review showed that underactive thyroid or a temporary decrease in thyroid hormone levels were uncommon. However, the conditions should be identified and treated early when needed to prevent potential future complications. Newborns, particularly those born premature, and children in their first 3 years with underlying conditions such as heart issues may be at higher risk for problems of the thyroid, a gland in the neck that releases hormones that help control many of the body’s functions.

What is FDA doing?

We have approved a new warning to the prescribing information for the entire class of iodinated contrast media (ICM) injections and monitoring recommendations for children 3 years or younger. The warning describes the risk of underactive thyroid or a temporary decrease in thyroid hormone levels. These risks and recommendations pertain to ICM given as an injection through an artery or vein.

What are ICM injections and how can they help my child?

ICM have been approved for decades and are drugs containing iodine given to patients to enhance the ability to see blood vessels, organs, and tissues on medical images such as X-rays or computed tomography (CT) scans (see Table 1 below for a list of products). This results in detailed images that can help health care professionals diagnose potential problems.

What should parents and caregivers do?

Parents and caregivers should talk to your child’s health care professional for additional information or if you have any questions or concerns about your child receiving an ICM injection. Babies and young children typically do not show any visible signs of thyroid problems and may need to be monitored by their health care professionals after receiving ICM.

What should health care professionals do?

Health care professionals should perform appropriate monitoring of patients from birth through 3 years for the possibility of hypothyroidism or a temporary decrease in thyroid hormone levels following exposure to ICM. Consider evaluating thyroid function within 3 weeks, especially in

term and preterm neonates and children with some underlying conditions. If thyroid dysfunction is detected, treat and monitor thyroid function as clinically needed to avoid future cognitive and other developmental disabilities.

Certain pediatric patients are at an increased risk, including those who are newborns or have very low birth weight, prematurity, or the presence of cardiac or other conditions such as those requiring care in neonatal or pediatric intensive care units. Patients with cardiac conditions may be at greatest risk since they often require high doses of contrast during invasive cardiac procedures.

What did FDA find?

Since 2015 when FDA first [alerted](#) the public about cases of underactive thyroid in infants receiving ICM, six new research studies evaluating this risk have been published.¹⁻⁶ We reviewed these six studies and the five earlier ones⁷⁻¹¹ published in the medical literature that assessed thyroid function in a range of 10 to 2,320 children from birth through 3 years who were exposed to ICM. Most cases of decreased thyroid hormone levels were temporary and did not require treatment. The reported rate ranged from 1 percent to 15 percent and tended to be higher in newborns, particularly those who were preterm. Patients with cardiac conditions were at greatest risk since they often require high doses of contrast during invasive cardiac procedures such as catheterization and CT. The time from ICM exposure to diagnosis ranged between 8.5 and 138 days, with most occurring within 3 weeks in some of the publications.

In 2015, we required the manufacturers of ICM products to conduct a study to investigate this safety issue further. However, we have concluded based on our review of the published studies¹⁻¹¹ that there is compelling evidence of a significant risk for underactive thyroid or a temporary decrease in thyroid hormone levels in newborns and children through 3 years after exposure to ICM; therefore, the study by the manufacturers is no longer needed.

What is my child's risk?

All medicines have side effects, but when used correctly as prescribed, the benefits of taking a medicine outweigh these risks. It is important to know that people respond differently to all medicines depending on their health, other medicines they are taking, the diseases they have, genetic factors, and many other factors. As a result, we cannot determine how likely it is that your child will experience underactive thyroid or a temporary decrease in thyroid hormone levels after receiving ICM. However, if your child is a newborn, has very low birth weight, was premature, has a heart condition, or was admitted to a neonatal or pediatric intensive care unit, they may be at higher risk after receiving ICM.

How do I report side effects from ICM?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving ICM or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

How can I get new safety information on medicines I’m prescribing or taking?

You can sign up for [email alerts](#) about Drug Safety Communications on medicines or medical specialties of interest to you.

Table 1. FDA Approved Iodinated Contrast Media Injections

| Generic name | Brand name(s) |
|-----------------------|--|
| iodixanol | Visipaque 270, 320 |
| iohexol | Omnipaque 140, 180, 240, 300, 350 |
| iopamidol | Isovue-200, 250, 300, 370 Isovue-M 200, 300 |
| iopromide | Ultravist 300, 370 |
| iothalamate meglumine | Conray, Conray 43 |
| ioversol | Optiray 300, 320, 350 |

Facts about Iodinated Contrast Media (ICM) Injections

- Also known as “contrast dye” or “X-ray dye,” ICM injections are drugs containing iodine that are used to enhance the ability to see blood vessels, organs, and tissues during medical imaging procedures.
- Procedures that use ICM include X-rays of blood vessels, joints, and organs, and some computed tomography (CT) scans.
- ICM are given as injections into arteries, veins, or other body cavities; however, the information in this Drug Safety Communication pertains to ICM given as an injection through an artery or vein.
- Common side effects associated with ICM include flushing in the face, nausea or vomiting, mild itchiness, and skin rash.

Additional Information for Parents and Caregivers

- X-ray scans and other types of [medical imaging](#) are important to help health care professionals diagnose a variety of conditions, but special care is needed after babies and young children receive injections of contrast media containing iodine, also called “contrast dye” or iodinated contrast media (ICM).
- Therefore, FDA recommends that newborns and children through 3 years have appropriate thyroid monitoring by their health care professionals after receiving ICM injections. The thyroid is a gland in the neck that releases hormones that help control many of the body’s functions.
- Underactive thyroid or a temporary decrease in thyroid hormone levels are uncommon in babies and young children after receiving ICM; however, newborns, particularly those born prematurely, and children in the first 3 years with underlying conditions such as heart issues may be at a higher risk.

- Babies and young children typically do not show any visible signs of underactive thyroid or temporary decrease in thyroid hormone levels. These forms of thyroid dysfunction can be evaluated through blood testing.
- Talk to your child's health care professional if your child has received or will receive an ICM injection, or you have questions or concerns about ICM.
- To help FDA track safety issues with medicines, report side effects from ICM or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for [email alerts](#) about Drug Safety Communications on medicines or medical specialties of interest to you.

Additional Information for Health Care Professionals

- FDA recommends monitoring of pediatric patients from birth through 3 years for the possibility of hypothyroidism or a temporary decrease in thyroid hormone levels following exposure to iodinated contrast media (ICM). Consider evaluating thyroid function within 3 weeks, especially in term and preterm neonates. If thyroid dysfunction is detected, treat and monitor thyroid function as clinically needed.
- Thyroid dysfunction characterized by hypothyroidism or a temporary decrease in thyroid hormone levels has been reported after single exposure and multiple exposures to ICM.
- Pediatric patients from birth through 3 years warrant closer monitoring to prevent an underactive thyroid during early life that may harm motor, hearing, and cognitive development and may require transient T4 replacement therapy.
- Certain pediatric patients are at an increased risk, including newborns and those having very low birth weight, prematurity, or the presence of cardiac or other conditions such as those requiring care in neonatal or pediatric intensive care units. Patients with cardiac conditions may be at greatest risk since they often require high doses of contrast during invasive cardiac procedures such as catheterization and computed tomography (CT).
- Counsel parents and caregivers about the risk of their child developing hypothyroidism or a temporary decrease in thyroid hormone levels after receiving ICM and inform them that follow-up monitoring may be performed.
- To help FDA track safety issues with medicines, report adverse events involving ICM or other medicines to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of this page.
- You can sign up for [email alerts](#) about Drug Safety Communications on medicines or medical specialties of interest to you.

Data Summary

Since 2015 when FDA first [alerted](#) the public about cases of underactive thyroid in infants receiving iodinated contrast media (ICM), several research studies evaluating this risk have been published.¹⁻⁶ We reviewed these six studies and the five earlier ones⁷⁻¹¹ published in the medical literature that assessed thyroid function in a total of 3,481 children from birth through 3 years who were exposed to ICM. Six studies were prospective and five were retrospective. Of the 11

studies, seven were conducted in the European Union, three in the United States, and one in Israel. Two studies, one in the United States and one in Israel, were larger studies with 2,320 and 843 children, respectively. Both monitored children exposed to ICM for onset of thyroid dysfunction within 1 year of exposure. The remaining nine studies included children who either had very low birth weight, a cardiac history, or were in intensive care unit.

Most reported cases were transient subclinical hypothyroidism and did not require treatment. The reported rate ranged from 1 percent to 15 percent and tended to be higher in neonates, particularly preterm neonates. Patients with cardiac conditions were at greatest risk since they often require high doses of contrast during invasive cardiac procedures such as catheterization and computed tomography (CT). The time from ICM exposure to diagnosis of thyroid dysfunction ranged between 8.5 and 138 days, with most occurring within 3 weeks in some of the publications.

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Related Information

[Iodinated Contrast Media \(ICM\)](#)

[Medline Plus: Diagnostic Imaging](#)

[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)

[Think It Through: Managing the Benefits and Risks of Medicines](#)