



Iodine-containing Contrast Agents for Medical Imaging: Drug Safety Communication - Rare Cases of Underactive Thyroid in Infants

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FDA 表示，使用含碘造影劑可能導致少數嬰兒出現甲狀腺功能低下的副作用，目前被通報的案例多為早產兒或是合併其他疾病。FDA 表示，現有證據顯示這種罕見的副作用為暫時性的，不經治療就可以緩解，而且副作用不會持續下去。FDA 已核准含碘造影劑廠商在仿單上加註相關訊息，但目前不會改變處方模式或是監測方式。FDA 會繼續監控相關安全訊息，如有進展會再進行公告，製造商也被要求須進一步針對這個安全議題進行研究。

建議

FDA 建議，嬰兒在使用含碘造影劑期間，父母與照顧者如有問題或疑慮應與醫護人員聯繫，嬰兒通常不會明顯表現出甲狀腺功能低下的跡象，醫護人員須依照仿單規範使用含碘造影劑，並依臨床情況判斷是否必須進行甲狀腺功能測試。

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AUDIENCE: Radiology, Endocrinology, Patient

ISSUE: FDA is advising that rare cases of underactive thyroid have been reported in infants following the use of contrast media containing iodine, also called “contrast dye,” for X-rays and other medical imaging procedures. In all of the reported cases, the infants were either premature or had other serious underlying medical conditions. Available evidence leads FDA to believe that this rare occurrence is usually temporary and resolves without treatment or any lasting effects. See the Drug Safety Communication for a data summary and a list of approved Iodinated Contrast Media Products.

FDA approved changes to the labels of all iodinated contrast media (ICM) products to include information about these cases. No changes to current prescribing, administration, or monitoring practices are recommended. FDA will continue to evaluate this issue and will update the public when there is additional information. Manufacturers of ICM products have been required to conduct a study to investigate this safety issue further.

BACKGROUND: Iodinated contrast media are drugs containing iodine that are given to patients to enhance the ability to see blood vessels and organs on medical images such as X-rays or computed tomography (CT) scans. These images provide greater detail when necessary to help health care professionals diagnose potential problems.

RECOMMENDATION: Parents and caregivers should contact their baby’s health care professional for additional information or if they have questions or concerns about their baby receiving an ICM product. Infants typically do not show any visible signs of underactive thyroid. Health care professionals should continue to follow the label recommendations for ICM products. They should continue to use their clinical judgment to determine if testing for underactive thyroid is necessary.

Table 1. FDA Approved Marketed Iodinated Contrast Media Products

Generic name	Brand name(s)
diatrizoate meglumine	Cystografin Cystografin Dilute
diatrizoate meglumine and diatrizoate sodium	MD-76R
iodipamide meglumine	Cholografin Meglumine
iodixanol	Visipaque 270, 320
iohexol	Omnipaque 140, 180, 240, 300, 350
iopamidol	Isovue-200, 250, 300, 370 Isovue-M 200, 300 Scanlux-300, 370
iopromide	Ultravist 150, 240, 300, 370
iothalamate meglumine	Conray Conray 30, 43
ioversol	Optiray 240, 300, 320, 350
ioxaglate meglumine and ioxaglate sodium	Hexabrix
ioxilan	Oxilan-300, 350