

As of: 11/20/15 1:00 PM
 Received: November 19, 2015
 Status: Pending Post
 Tracking No. 1jz-8mch-s2a9
 Comments Due: February 16, 2016
 Submission Type: Web

PUBLIC SUBMISSION

Docket: NRC-2015-0020

Nuclear Request for Sodium Iodide I-131 Treatment and Patient Release Information

Comment On: NRC-2015-0020-0014

Sodium Iodide I-131 Patient Release Information Collection; Request for Information

Document: NRC-2015-0020-DRAFT-0013

Comment on FR Doc # 2015-29027

11/16/2015
 80 FR 70843

1

Submitter Information

Name: Wayne Adams

Address:

5444 South Green Street
 Salt Lake City, UT, 84123

Email: wadams@mtnmedical.com

RECEIVED

2015 11/20 11:00

RULES AND DIRECTIVES
 BOARD
 CHIEF

General Comment

I am an MD with Mountain Medical Physician Specialists and I work Intermountain Healthcare Hospitals in Utah. I am attaching the materials that I put together for our patients treated with radioactive iodine, both for hyperthyroidism and thyroid cancer.

I am also working with Intermountain Healthcare to put together patient information videos which patients will be able to view online. We are just starting production of the thyroid cancer video that should be out in a few months. The second video script for hyperthyroid patients has been finished and is also scheduled to be produced soon.

Attachments

INSTRUCTIONS FOR PATIENTS RECEIVING IODINE

INSTRUCTIONS FOR Thyroid Cancer PATIENTS RECEIVING IODINE

SUNSI Review Complete

Template = ADM - 013

E-RIDS= ADM-03

Add= *R-B. HOWE (DBH)*



INSTRUCTIONS FOR PATIENTS RECEIVING IODINE-131 FOR HYPERTHYROIDISM

Your doctor has requested that you be treated with radioactive iodine because of your hyperthyroid condition. This document contains descriptions of precautions that you should follow as well as risks associated with this treatment and other general instructions.

GERNERAL INFORMATION/INSTRUCTIONS

1. There are alternative treatments for hyperthyroidism other than administration of Iodine-131, an orally administered radiopharmaceutical. These treatments include surgery and oral medications such as PTU and Methimazole. Be sure to discuss these alternative treatments with your referring MD prior to treatment.
2. In order to allow the iodine-131 to be absorbed by your intestines, we recommend that you do not eat or drink for about 4 hours prior to and for 2 hours after ingesting the I-131. Taking a small amount of water with your usual necessary medications is okay.
3. The administered I-131 is given orally either in pill form or as a liquid.
4. Beginning a few hours after your treatment, it is important that you drink lots of fluids over the next few days as well as urinating as frequently as possible. This will decrease your whole body radiation dose and especially limit the radioactivity exposure of the urinary bladder. Periodic voiding of the bladder overnight is also recommended every few hours for the first night or two.
5. You may expect to see your hyperthyroid symptoms improve within 6-8 weeks and hypothyroidism may occur within two-three months of therapy. The maximum benefit usually occurs 3 to 6 months after treatment. You will require close follow up of your thyroid function measurements by your referring physician.
6. I-131 therapy cannot be given to patients who are pregnant because of potential damage to the developing fetus. If you are a premenopausal woman, you will be asked to undergo a pregnancy test prior to

treatment with radioactive iodine. This test is typically performed either the day of treatment or 1-2 days prior to the date of treatment with I-131. In addition, because a serum pregnancy test could be negative for about 10 days after conception begins, we recommend that you do not have unprotected intercourse for 10 days prior to your I-131 treatment.

7. You should wait 6 to 12 months following receiving iodine-131 therapy before trying to conceive a child.
8. Women who are breast-feeding or lactating cannot be treated with I-131.
9. For up to 3 months or more following radioiodine treatment you may set off radiation detectors at: national borders, airports, bus and train stations, tunnels, bridges, trash collection sites and even your place of employment.

RISKS

1. Permanent hypothyroidism may occur within 2 to 3 months of I-131 therapy. The goal of treatment of your condition with radioactive iodine is to achieve a non-hyperthyroid status, either a euthyroid (normal thyroid function) state or hypothyroidism (loss of the ability to make adequate thyroid hormone). Most patients with Graves disease will eventually become permanently hypothyroid and need to take thyroid hormone replacement medication for the rest of their lives. This medication consists of a small pill, often Synthroid, usually taking once a day. Patients with permanent hypothyroidism will require long-term follow-up by their physicians. Permanent hypothyroidism is less common in patients with nodular goiters though still commonly occurs. For more on hypothyroidism, see the following link- <http://www.thyroid.org/what-is-hypothyroidism>
2. On the other hand, some patients never become hypothyroid after the first treatment and may need to be retreated one or more times. If retreatment is needed, a minimum period of about 6 months is usually waited before retreating.
3. Transient worsening of hyperthyroidism can occur in the first 2 weeks following treatment of hyperthyroid patients with I-131. A severe form of this called "thyroid storm" can be life threatening although is quite rare. Symptoms of thyroid storm include cardiovascular problems such as experiencing rapid heart rates over 140 beats per

- minute and congestive heart failure. Patients can also experience a high fever, severe anxiety and agitation. Patients experiencing these symptoms should seek immediate medical care. Prior to treatment with I-131, some patients will be placed on oral beta-blockers such as propranolol, which limit the effects of thyroid storm on the heart rate.
4. Recurrent laryngeal nerve palsy (leading to hoarseness) and dysgeusia (altered or distorted sense of taste) can be temporary or permanent but this is very uncommon.
 5. 1% to 5% of patients experience a mildly painful radiation thyroiditis resulting in neck pain after treatment. This can usually be treated successfully with acetaminophen (Tylenol). We would prefer that you do not take large doses of non-steroidal anti-inflammatory drugs such as Ibuprofen for a few days following treatment.
 6. Graves' Ophthalmopathy (thyroid eye disease) has been reported to worsen or occur following treatment with iodine 131, especially in smokers.
 7. The treatment may affect the way food tastes, usually a short-term side effect.
 8. There is no convincing scientific evidence of increased risk of I-131 treatment of hyperthyroid patients causing subsequent thyroid cancer or other cancers nor is there an increased risk of infertility or birth defects caused by this treatment.

RADIATION SAFETY PRECAUTIONS

For patients receiving 33 mCi of I-131 or less.

1. Sleep alone and abstain from sexual intercourse for one week after therapy. Do not sleep with a pregnant partner, infant or child for two weeks.
2. Use separate eating utensils and plates. Disposable plates and utensils are not necessary.
3. Double flush the toilet after each use and wash hands for 20 seconds afterwards.
4. Men should urinate sitting down to avoid contaminating the area around the toilet.
5. Please discard any tissues containing mucus contaminated with iodine 131 into the toilet and not into the trashcan.
6. Infants and small children requiring feeding, changes of clothing, and similar care from the treated parent will require another caregiver for up to a week.

7. Pregnant women and children may have about 10 min of zero distance per day from the patient but otherwise should maintain a distance of about 0.9–1.8 m (3–6 ft), as if the patient had a bad cold.
8. There are no other restrictions on a patient being with other adults.
9. There is no hazard to any member of the family arising from sites where a patient sits, what the patient has touched, or what the patient cooks.
10. Family members should not ingest items contaminated by patient saliva or urine.

References:

Silberstein et al. The SNM Practice Guideline for Therapy of Thyroid Disease with ¹³¹I 3.0*. J Nucl Med. 2012; 53: 1633-1651.



INSTRUCTIONS FOR PATIENTS RECEIVING IODINE-131 FOR THYROID CANCER

Your doctor has requested that you be treated with radioactive iodine because of your thyroid cancer. This document contains descriptions of precautions that you should follow as well as risks associated with this treatment and other general instructions.

GERNERAL INFORMATION/INSTRUCTIONS

1. Oral Iodine-131 treatment is used in patients with a history of thyroid cancer in order to: destroy residual thyroid cancer following thyroidectomy; destroy thyroid cancer which has recurred locally or has spread distantly; as well as to kill any residual normal thyroid tissue following thyroidectomy.
2. Successful treatment with radioactive iodine depends on adequate levels of thyroid stimulating hormone (TSH) in the blood. TSH measurements are obtained in those patients who are taken off of their thyroid hormone replacement medication (thyroid hormone withdrawal) prior to treatment in order to ensure the TSH level is adequate. An alternative to withdrawal is intramuscular administration of Thyrogen (recombinant TSH) given approximately 48 hours and 24 hours prior to your I-131 treatment. Whether or not you will receive withdrawal preparation or Thyrogen will depend on your referring physician's preference and your insurance coverage.
3. If you are receiving your initial treatment with Iodine 131 (occasionally patients need more than one treatment), a 24-hour uptake measurement with a very small dose of I-131 is usually performed. We perform this measurement to determine how much residual thyroid tissue remains in your neck (postsurgical remnant). Too much residual tissue could prevent our prescribing as large of a dose of I-131 for treatment as we would prefer. On follow-up treatments, if needed, this uptake measurement may or may not be done. In retreatment patients a whole-body thyroid scan prior to additional treatment oftentimes will be performed.

4. Beginning a few hours after your treatment, it is important that you drink lots of fluids other than milk (2.5-3 liters/day or 2.5-3 quarts/day) over the next several days as well as urinating as frequently as possible. This will decrease your whole body radiation dose and especially limit the radioactivity exposure of the urinary bladder. Periodic voiding of the bladder overnight is also recommended every few hours for the first few nights.
5. I-131 therapy cannot be given to patients who are pregnant because of potential damage to the developing fetus. If you are a premenopausal woman, you will be asked to undergo a pregnancy test prior to treatment with radioactive iodine. This test is typically performed either the day of treatment or 1-2 days prior to the date of treatment with I-131. In addition, because a pregnancy test could be negative in the first several days after pregnancy begins, we recommend that you do not have unprotected intercourse for 10 days prior to your I-131 treatment.
6. You should wait 6 to 12 months following receiving iodine-131 therapy before trying to conceive a child.
7. Women who are breast-feeding or lactating cannot be treated with I-131.
8. Please inform your treating physician if you have a diagnosis of kidney failure.
9. Receiving intravenous contrast containing iodine, such as for a CT scan, can delay treatment with I-131 for two months.
10. After your treatment dose, a whole body scan will usually be performed up to one week later.
11. On your drive home from receiving your radioactive treatment dose, it is preferable that you drive alone, but if this is not possible, you should sit in the back seat as far from the driver as is possible. The driver cannot be pregnant.
12. Since thyroid cancer can recur up to 20 years or more after initial therapies, it is important that you follow-up with your doctor routinely in order to detect new sites of thyroid cancer as well as to make sure that your TSH levels are kept suppressed.
13. For up to a month or more following radioiodine treatment you may set off radiation detectors at: national borders, airports, bus and train stations, tunnels, bridges, trash collection sites and even your place of employment.

Preparation

1. Being placed on a low iodine diet for one to two weeks prior to treatment with I-131 has been shown to increase the radioiodine uptake in your thyroid tissues and improve the rate of ablation of these tissues. The following is a link to a website that you may find useful in adhering to low iodine diet -
<http://www.thyca.org/download/document/231/Cookbook.pdf>
2. You will want to stay on the low iodine diet approximately 2 days following your treatment.
3. Some referring physicians ask their patients given Thyrogen to stop taking their thyroid hormone replacement medication for up to several days prior to I-131 treatment. This is because replacement thyroid hormone itself contains a small amount of nonradioactive iodine, which could potentially decrease the uptake of the radioactive I-131 by your thyroid tissues.
4. In order to allow the iodine-131 to be absorbed by your intestines, we recommend that you do not eat or drink for about 4 hours prior to and for 2 hours after ingesting the I-131. This is true for both the uptake measurement dose as well as the treatment dose. Taking a small amount of water with your usual necessary medications is okay.
5. Have at least one bowel movement per day after treatment. Use stool softeners (not laxatives) if necessary.

RISKS

1. Early side effects include oral mucositis (painful inflammation and ulceration of the mucous membranes of the mouth and intestines), nausea, occasional vomiting, sialadenitis (salivary gland inflammation), and dysgeusia (loss of taste or unusual, often metal-like, alterations in taste).
2. Permanent damage to the salivary glands or Xerostomia is the lack of the ability to produce adequate mucous and can result in a temporarily or permanently "dry mouth". Complication of xerostomia includes dysgeusia, excessive dental carries (cavities), and sialolithiasis (forming stones in the salivary gland ducts). Maintaining a high degree of hydration is thought to be helpful in addressing the salivary gland problems. Additionally, stimulating salivary flow by sucking on sugar-free hard candy, chewing gum etc. may be helpful in protecting

against this side effect. Performing this activity every few hours for the first four days after treatment and every 3 hours or so at night during this time period is suggested. The topic of protection of the salivary glands is somewhat controversial but the current thinking is that the above process will help prevent damage to your salivary glands. This should be started about two hours after taking the dose of I-131.

3. Oral mucositis with small, painful mouth ulcerations may often be prevented by gentle brushing of the entire oral mucosa with a soft toothbrush about every 3–4 hours for 4–7 days while awake; this can be extended to every 3 h at night for the first 4 days after treatment.
4. Permanent infertility can rarely occur in the males receiving multiple large doses of I-131.
5. Painful thyroiditis (pain and swelling occurring directly over your thyroid tissue) is more likely to occur if there is a sizeable postsurgical remnant present and may be associated with neck swelling, impingement on the trachea, and, rarely, recurrent laryngeal nerve paralysis resulting in hoarseness.
6. A transient decrease in white blood cell count and platelet counts can occur for up to 6-10 weeks, which could cause an increase in your susceptibility to infection or bleeding. This is a rare side effect and seen only with very high doses.
7. Damage to the tear producing glands of the eyes can also occur resulting in either excessive or absent tear production.
8. Uncommonly, after high doses of I-131, development of other cancers has been reported. These include cancers of the stomach, bladder, colon, and salivary glands as well as melanoma and leukemia. These usually occur after more than one therapeutic dose.

RADIATION SAFETY PRECAUTIONS

	mCi (MBq) administered			
	50 (1850)	100 (3700)	150 (5550)	200 (7400)
Nighttime restrictions	Days/24-h cycles			
Sleep in a separate (6-foot separation) bed from adults for days shown.	1	1	2	4
Sleep in a separate bed from pregnant partners, infant, or child for days shown.	6	13	18	21
Daytime restrictions				
You may return to work after days shown.	1	1	1	1
Maximize your distance (6 feet) from children and pregnant women for days shown.	1	1	1	1
Avoid extended time in public places for days shown.	1	1	1	1

1. Sleep alone for time period as indicated in table above.

2. The daytime restrictions in the above table assumes you will not be in a situation where someone you work with, or the public will be closer to you than 3 feet of distance. Staying even further away, preferably 6 or more feet is preferred.
3. Use separate eating utensils and plates. Disposable plates and utensils are not necessary.
4. Double flush the toilet after each use and wash hands for 20 seconds afterwards.
5. Men should urinate sitting down to avoid contaminating the area around the toilet.
6. Please discard any tissues containing mucus contaminated with iodine 131 into the toilet and not into the trashcan.
7. Infants and small children requiring feeding, changes of clothing, and similar care from the treated parent will require another caregiver for up to a week.
8. There is no hazard to any member of the family arising from sites where a patient sits, what the patient has touched, or what the patient cooks.
9. Family members should not ingest items contaminated by patient saliva or urine.

References:

Silberstein et al. The SNM Practice Guideline for Therapy of Thyroid Disease with ¹³¹I 3.0*. J Nucl Med. 2012; 53: 1633-1651.

Sisson et al. Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine 131I: Practice Recommendations of the American Thyroid Association. Thyroid. 2011; 21; 335-346.