

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Choline C 11 Injection safely and effectively. See full prescribing information for Choline C 11 Injection.

Choline C 11 Injection, for intravenous use
Initial U.S. Approval: 2012

INDICATIONS AND USAGE

Choline C 11 Injection is a radioactive diagnostic agent for positron emission tomography (PET) imaging of patients with suspected prostate cancer recurrence and non-informative bone scintigraphy, computerized tomography (CT) or magnetic resonance imaging. In these patients, ¹¹C-choline PET imaging may help identify potential sites of prostate cancer recurrence for subsequent histologic confirmation. Suspected prostate recurrence is based upon elevated blood prostate specific antigen (PSA) levels following initial therapy. In clinical studies, images were produced with PET/CT coregistration.

Limitation of Use: ¹¹C-choline PET imaging is not a replacement for histologic verification of recurrent prostate cancer (1).

DOSAGE AND ADMINISTRATION

- Aseptically withdraw Choline C 11 Injection from its container and administer 370 to 740 MBq (10 to 20 mCi) as a bolus intravenous injection. The radioactivity dose (370 to 740 MBq, 10 to 20 mCi) is chosen based on patient body dimensions and the characteristics of the image acquisition system (2.1).
- Initiate imaging immediately after administration of Choline C 11 Injection and acquire static emission images 0 to 15 minutes from the time of injection (2.5).
- The effective radiation absorbed dose from 740 MBq (20 mCi) dose of Choline C 11 Injection is approximately 3.22 mSv (0.32 rem) in an adult (2.4).
- Image interpretation: Refer to full prescribing information (2.5).

DOSAGE FORMS AND STRENGTHS

- Choline C 11 injection contains 148 MBq/mL to 1,225 MBq/mL (4 mCi/mL to 33.1 mCi/mL) of ¹¹C-choline at EOS (End of Synthesis) calibration time in aqueous 0.9% sodium chloride solution (approximately 10 mL volume) (3).

CONTRAINDICATIONS

None (4).

WARNINGS AND PRECAUTIONS

- Imaging errors have been reported; blood PSA levels < 2 ng/mL have been associated with poor imaging performance (5.1).
- Allergic reactions: have emergency resuscitation equipment and personnel readily available (5.2).
- Radiation risk: Choline C 11 Injection contributes to a patient's long-term cumulative radiation exposure. Ensure safe handling to protect the patient and health care worker (5.3).

ADVERSE REACTIONS

Exclusive of an uncommon, mild injection site reaction, no other adverse reactions have been reported (6).

To report SUSPECTED ADVERSE REACTIONS, contact Division of Nuclear Medicine, Department of Radiology, Mayo Clinic at 507-284-2511 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG INTERACTIONS

Colchicine and androgen-deprivation therapeutic drugs may interfere with ¹¹C-choline PET/CT imaging performance (5.1).

See 17 for PATIENT COUNSELING INFORMATION

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Choline C 11 Injection is indicated for positron emission tomography (PET) imaging of patients with suspected prostate cancer recurrence and non-informative bone scintigraphy, computerized tomography (CT) or magnetic resonance imaging (MRI). In these patients, ¹¹C-choline PET imaging may help identify potential sites of prostate cancer recurrence for subsequent histologic confirmation. Suspected prostate recurrence is based upon elevated blood prostate specific antigen (PSA) levels following initial therapy. In clinical studies, images were produced with PET/CT coregistration.

Limitation of Use: ¹¹C-choline PET imaging is not a replacement for histologic verification of recurrent prostate cancer.

2 DOSAGE AND ADMINISTRATION

2.1 Radiation Safety - Drug Handling

Choline C 11 Injection is a radioactive drug and should be handled with appropriate safety measures to minimize radiation exposure during administration. Use waterproof gloves and effective shielding when handling Choline C 11 Injection. Radiopharmaceuticals, including Choline C 11 Injection, should only be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radioactive materials, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

2.2 Recommended Dose and Administration Instructions

The recommended dose is 370 to 740 MBq (10 to 20 mCi) administered as a bolus intravenous injection. The radioactivity dose (370 to 740 MBq, 10 to 20 mCi) is chosen based on patient body dimensions and the characteristics of the image acquisition system

- Inspect Choline C 11 Injection visually for particulate matter and discoloration before administration. Do not use the drug if the solution contains particulate matter or is discolored.
- Aseptically withdraw Choline C 11 Injection from its container and administer the drug as a bolus through a peripheral venous catheter.
- Dispose of any unused drug in a safe manner, in compliance with applicable regulations.

2.3 Patient Preparation

Prior to administration of Choline C 11 Injection:

- Fasting for at least six hours is recommended to minimize the potential for dietary choline interference with radioactivity uptake in tissue.
- Ensure that the patient is well hydrated and encourage voiding when imaging is completed.

2.4 Radiation Dosimetry

The estimated radiation absorbed doses for adults from intravenous injection of Choline C 11 Injection are shown in Table 1. These estimates are calculated from data in Tolvanen ¹ and using OLINDA/EXM (Organ Level Internal Dose Assessment/Exponential Modeling) software from Vanderbilt University.²

Table 1: Estimated Radiation Absorbed Dose Per Unit Activity for Adults, Choline C 11 Injection

Organ/Tissue	Mean Absorbed Dose Per Unit Administered Activity ($\mu\text{Gy}/\text{MBq}$) ^b
Adrenals	3.59
Bone - Osteogenic Cells	4.81
Bone - Red Marrow	1.90
Brain	1.16
Breast	1.39
Gallbladder Wall	4.54
GI ^a – Lower Large Intestine Wall	1.81
GI ^a - Small Intestine	2.35
GI ^a - Stomach Wall	6.00
GI ^a – Upper Large Intestine Wall	6.41
Heart wall	3.43
Kidneys	20.62
Liver	20.11
Lungs	4.59
Muscle	2.54
Ovaries	2.02
Pancreas	29.19
Skin	1.22
Spleen	9.16
Testes	1.36
Thymus	1.69
Thyroid	1.49
Urinary Bladder Wall	3.41
Uterus	1.96
Total body	2.97
Effective Dose ($\mu\text{Sv}/\text{MBq}$) ^c	4.35

^a Gastrointestinal

^b Assumed radiation weighting factor, w_r , (formerly defined as quality factor, Q) of 1 for conversion of absorbed dose (Gray or rad) to dose equivalent (Sieverts or rem) for C 11. To obtain radiation absorbed dose in rad/mCi from the above table, multiply the dose in $\mu\text{Gy}/\text{MBq}$ by 0.0037, (e.g., $3.59 \mu\text{Gy}/\text{MBq} \times 0.0037 = 0.0133 \text{ rad}/\text{mCi}$).

^c Radiation tissue weighting factors, w_T , used in the calculation of effective dose are from 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication 60 (1991). To obtain radiation absorbed dose in rem/mCi from above table, multiply the dose in $\mu\text{Gy}/\text{MBq}$ by 0.0037, (e.g., $4.35 \mu\text{Gy}/\text{MBq} \times 0.0037 = 0.0161 \text{ rem}/\text{mCi}$).

The effective dose resulting from a 740 MBq (20 mCi) dosage of Choline C 11 Injection is 3.22 mSv in an adult, ($740 \times 4.35 = 3219 \mu\text{Sv} = 3.2 \text{ mSv}$). The use of a CT scan to calculate attenuation correction for reconstruction of ¹¹C-choline images (as done in PET/CT imaging) will add radiation exposure. Based upon current scanning techniques, an effective dose of 5.8 mSv would be added from CT scanning. The actual radiation dose is operator, scanner, and patient dependent. The total radiation exposure from ¹¹C-choline administration and subsequent scan on a PET/CT scanner is estimated to be 9.0 mSv (3.2 mSv + 5.8 mSv).

2.5 Imaging Guidelines

- Initiate image acquisition immediately after administration of Choline C 11 Injection. Imaging is typically performed from the base of the pelvis to the base of the skull.
- Acquire static emission images 0 to 15 minutes from the time of injection.
- Localized uptake of ¹¹C-choline in a site suspicious for prostate cancer recurrence (a positive image) is determined by comparison of the anatomical relationship of concentrated radioactivity to the

neighboring tissue background, exclusive of the radioactivity physiologically accumulated within the pancreas, liver, spleen, kidney and colon.

3 DOSAGE FORMS AND STRENGTHS

Choline C 11 Injection contains 148 MBq/mL to 1,225 MBq/mL (4 mCi/mL to 33.1 mCi/mL) of ^{11}C -choline at End of Synthesis (EOS) calibration time in aqueous 0.9% sodium chloride solution (approximately 10 mL volume).

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Imaging Errors

Imaging errors have been reported with ^{11}C -choline PET and PET/CT imaging. A negative image does not rule out the presence of recurrent prostate cancer and a positive image does not confirm the presence of recurrent cancer. ^{11}C -choline uptake is not specific for prostate cancer and may occur with other types of cancer (such as lung carcinoma and brain tumors). Clinical correlation, including histopathological evaluation of the suspected recurrence site, is essential to proper use of the PET imaging information.

- Blood PSA levels < 2 ng/mL have been associated with poor performance of ^{11}C -choline PET imaging (higher numbers of false positive and false negative results) [*see Clinical Studies (14)*].
- Tissue inflammation as well as prostatic hyperplasia have been associated with false positive ^{11}C -choline PET images.
- Concomitant colchicine or androgen-deprivation therapeutic drugs (such as luteinizing hormone-releasing analogs and anti-androgen drugs) may interfere with ^{11}C -choline PET imaging. One published report of ^{18}F -methylcholine PET imaging indicated that discontinuation of colchicine for two weeks resolved the colchicine effect. The impact of discontinuation of androgen-deprivation therapy upon ^{11}C -choline PET imaging has not been established [*see Drug Interactions (7)*].

5.2 Allergic Reactions

As with any injectable drug product, allergic reactions and anaphylaxis may occur. Emergency resuscitation equipment and personnel should be immediately available.

5.3 Radiation Risks

Choline C 11 Injection contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Safe handling should be ensured to minimize radiation exposure to the patient and health care workers [*see Dosage and Administration (2.1)*].

6 ADVERSE REACTIONS

Exclusive of an uncommon, mild injection site reaction, no adverse reactions to ^{11}C -choline have been reported.

7 DRUG INTERACTIONS

Colchicine and androgen-deprivation therapeutic drugs have been reported to interfere with choline-based PET imaging [*see Warnings and Precautions (5.1)*].

The impact of androgen-deprivation therapeutic drugs upon ^{11}C -choline PET imaging may depend upon the hormonal responsiveness of a patient's recurrent prostate cancer. Clinical studies have not established this relationship but published reports suggest ^{11}C -choline PET imaging may be productive in patients with "hormone resistant" recurrent prostate cancer even if the patients are receiving anti-androgen therapy. Imaging may prove unproductive or misleading due to failed or insufficient ^{11}C -choline uptake in patients with hormone-responsive cancer if the patients are receiving androgen-deprivation therapy.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Choline C 11 Injection is not indicated for use in females. There are no data on the use of choline C 11 in pregnant women to evaluate for any drug-associated risks of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with choline C 11. However, all radiopharmaceuticals, including choline C 11 injection have the potential to cause fetal harm depending on the stage of fetal development and the magnitude of the radiation dose.

8.2 Lactation

Risk Summary

Choline C 11 Injection is not indicated for use in females. There are no data on the presence of choline C 11 in human milk, the effect on the breastfed infant, or the effect on milk production.

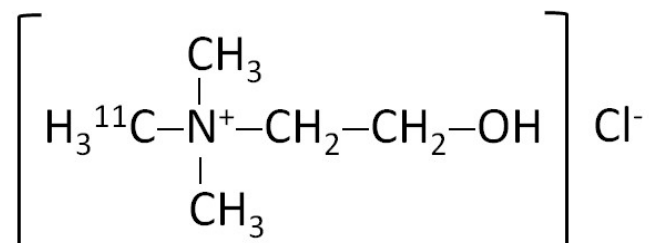
8.4 Pediatric Use

The safety and effectiveness of Choline C 11 Injection have not been established in pediatric patients.

11 DESCRIPTION

11.1 Chemical Characteristics

Choline C 11 Injection is a radioactive diagnostic agent for intravenous use. The active ingredient, ^{11}C -choline, has the molecular formula of $\text{C}_4^{11}\text{CH}_{14}\text{NOCl}$ with a molecular weight of 138.63 g and has the following chemical structure:



Choline C 11 Injection is provided as a ready to use sterile, pyrogen-free, clear and colorless solution. Each mL contains 148 MBq to 1,225 MBq (4 mCi to 33.1 mCi) of ^{11}C -choline at EOS calibration time in aqueous 0.9% sodium chloride solution. The pH of the solution is between 4.5 and 7.5.

11.2 Physical Characteristics

Carbon 11 is a cyclotron-produced radionuclide that decays to Boron 11 by positron emission and has a physical half life of 20.4 minutes (Table 2).

Table 2: Principal Radiation Emission Data for ¹¹C

Radiation/Emission	% Per Disintegration	Energy
Positron (β^+)	99.76	960.2 keV (Max.)
Gamma (\pm)*	199.5	511 keV

*Produced by positron annihilation

The specific gamma ray constant (point source air kerma coefficient) for ¹¹C-choline is 5.8 R/mCi-hr at 1 cm. Selected coefficients of attenuation are listed in Table 3 as a function of lead shield thickness. For example, the use of 39 mm thickness of lead will attenuate the external radiation by a factor of about 1,000.

Table 3: Radiation Attenuation of 511 keV Photons by lead (Pb) shielding

Shield Thickness (Pb) mm	Coefficient of Attenuation
4	0.5
8	0.25
13	0.1
26	0.01
39	0.001
52	0.0001

Table 4 lists fractions remaining at selected time intervals from the calibration time. This information may be used to correct for physical decay of the radionuclide.

Table 4: Physical Decay Chart for ¹¹C

Minutes	Fraction Remaining
0*	1.000
5	0.844
10	0.712
15	0.600
20	0.507
25	0.427
30	0.360

*Calibration time

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Choline C 11 Injection is a radiolabeled analog of choline, a precursor molecule essential for the biosynthesis of cell membrane phospholipids. Choline is involved in synthesis of the structural components of cell membranes, as well as modulation of trans-membrane signaling. Increased phospholipid synthesis (i.e., increased uptake of choline) has been associated with cell proliferation and the transformation process that occurs in tumor cells.

12.2 Pharmacodynamics

In a study of men with prostatic hyperplasia or primary prostate cancer, PET imaging showed ^{11}C -choline radioactivity accumulated rapidly within the prostate; uptake appeared to peak by five minutes following injection of the drug and activity was retained over the subsequent 30 minute scanning period. Little uptake was observed in the bladder and rectum.

12.3 Pharmacokinetics

Distribution: ^{11}C -choline distributes mainly to the pancreas, kidneys, liver, spleen and colon [see *Dosage and Administration* (2.4)]. Based upon the relatively low urinary excretion of radioactivity, renal distribution is predominantly to the organ itself, rather than via formation of urine.

Metabolism: Following intravenous administration, ^{11}C -choline undergoes metabolism resulting in the detection of ^{11}C -betaine as the major metabolite in blood. In a study of patients with prostate cancer or brain disorders, the fractional activities of ^{11}C -choline and ^{11}C -betaine in human arterial plasma appeared to reach a plateau within 25 minutes, with ^{11}C -betaine representing $82\% \pm 9\%$ of the total ^{11}C detected at that time point. A small amount of unmetabolized ^{11}C -choline was detected within the blood at the final sampling time point (40 minutes).

Elimination: Urinary excretion of ^{11}C -choline was $< 2\%$ of the injected radioactivity at 1.5 hours after injection of the drug. The rate of ^{11}C -choline excretion in urine was 0.014 mL/min.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term studies have not been performed to evaluate the carcinogenic potential of Choline C 11 Injection. The mutagenic potential of Choline C 11 Injection has not been adequately evaluated; however, any radiopharmaceutical, including Choline C 11 Injection, has the potential to be mutagenic. The effect of Choline C 11 Injection on fertility has not been evaluated.

14 CLINICAL STUDIES

A systematic review of published reports identified four studies that contained data sufficient to compare ^{11}C -choline PET imaging to histopathology (truth standard) among patients with suspected prostate cancer recurrence and non-informative conventional imaging (for most patients, CT or MRI). In general, the suspected recurrence criteria consisted of at least two sequential PSA levels of > 0.2 ng/mL for men who had undergone prostatectomy and PSA levels of ≥ 2 ng/mL above the post-therapy nadir for men who had undergone radiotherapy. The studies were predominantly single clinical site experiences and image acquisition generally surveyed radioactivity distribution from the base of the pelvis to the base of the skull.

Prospective studies: Two studies examined the ability of ^{11}C -choline PET/CT to detect prostate cancer in pelvic and/or retroperitoneal lymph nodes among patients who had previously undergone radical prostatectomy. Both studies used a truth standard of lymph node histopathology. ^{11}C -choline images were interpreted by readers masked to clinical information; surgical resection of lymph nodes was performed by surgeons aware of the ^{11}C -choline PET/CT results.

In Study One³, 25 patients who underwent ^{11}C -choline PET/CT and conventional imaging (CT or MRI) were scheduled to undergo pelvic or pelvic plus retroperitoneal lymphadenectomy following the imaging identification of suspected lymph node metastases. The median PSA was 2.0 ng/mL (range 0.2 to 23.1 ng/mL). The study excluded subjects with metastatic disease detected by bone scintigraphy or isolated prostatic fossa recurrence. Among the 25 patients, 21 had positive ^{11}C -choline PET/CT scans;

histopathology verified cancer in 19 of these patients. Lymph node histopathology detected no cancer among the four patients who had surgery based only on positive conventional imaging; ¹¹C-choline PET/CT was negative in all four patients. The study report included information for patients who had non-informative conventional imaging (CT or MRI, bone scintigraphy and transrectal ultrasound), as shown in Table 5.

In Study Two⁴, 15 patients were scheduled to undergo pelvic or pelvis plus retroperitoneal lymphadenectomy solely based upon positive ¹¹C-choline PET/CT imaging in the setting of negative conventional imaging (ultrasound and/or CT and/or MRI and/or bone scintigraphy). The median PSA was 2.0 ng/mL (range 1.0 to 8.0 ng/mL); all patients had previously undergone radical prostatectomy. Eight of the 15 patients had cancer verified by lymph node histology; histology detected no cancer in seven patients.

Retrospective Studies: Two studies were retrospective reviews of patients who underwent ¹¹C-choline PET/CT and had histopathology obtained from biopsy of the prostatic fossa or other suspected recurrence sites.

In Study Three⁵, ¹¹C-choline PET/CT imaging was performed among 36 patients with suspected prostate cancer recurrence and 13 subjects without suspected recurrence (controls). Prostatic fossa biopsies were performed among the patients with suspected recurrence. All the patients and control subjects had previously undergone radical prostatectomy; patient with suspected recurrence had no evidence of cancer using conventional clinical evaluations, including trans-rectal ultrasound and bone scintigraphy. PET/CT scans were interpreted by readers masked to clinical information. Median PSA was 2.0 ng/mL (range 0.3 – 12.1 ng/mL) for patients with suspected recurrence and 0.1 ng/mL (range 0.0 – 0.2 ng/mL) in control subjects. Prostatic fossa biopsy showed cancer in 33 of the 36 patients with suspected recurrence. PET/CT scans were positive in 25 of the 36 patients; two patients had false positive scans (one scan in a control subject and one scan in a suspected recurrence subject who had no cancer detected on prostatic fossa biopsy). Among the 13 control subjects, 12 had negative PET/CT scans.

In Study Four^{6,7}, 34 patients with negative conventional imaging underwent ¹¹C-choline PET/CT and subsequently had biopsies of suspected recurrence sites. The median PSA level of the 34 patients was 3.9 ng/mL (range 0.2 to 65.0 ng/mL); 22 of the patients had previously undergone radical prostatectomy and 12 had received other therapy (radiotherapy, anti-androgen therapy or cryotherapy). ¹¹C-choline PET/CT images were positive in 30 patients and negative in four patients. Cancer was verified by histopathology in 29 patients; 25 had positive PET/CT images and four had negative PET/CT images. Five patients with positive PET/CT images did not have cancer confirmed with histopathology.

As shown in Table 5, within each study at least half the patients with non-informative conventional imaging had positive ¹¹C-choline PET/CT images and histologically verified recurrent prostate cancer.

Table 5 ¹¹C-Choline PET/CT Results among Patients with Non-informative Conventional Imaging and a Histopathology Truth Standard

Study	Patients, n				
	Total	True Positive	False Positive	True Negative	False Negative
One	13	11	2	ND*	ND*
Two	15	8	7	ND*	ND*
Three	36	23	1	2	10
Four	34	25	5	0	4

*ND = not determined

In Studies Three and Four, PSA levels were generally lower for patients with negative ¹¹C-choline PET/CT results than for patients with positive results. In Study Three, the median PSA was 2.6 ng/mL (range 0.6 – 12.1 ng/mL) among the 23 patients with true positive images; nine out of 11 patients with false negative or false positive images had PSA levels < 2 ng/mL. In Study Four, the median PSA was 4.2 ng/mL (range 0.2 – 65.0 ng/mL) among the 25 patients with true positive images; PSA levels < 2 ng/mL were observed in four of the nine patients with false negative or false positive images. These data, combined with other published reports, suggest that ¹¹C-choline PET imaging performance may be more reliable among patients with blood PSA levels > 2 ng/mL, compared to patients with lower levels.

15 REFERENCES

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- ⁶Mitchell C, Kwon E, Lowe V, Hung J, Rangel L, Karnes RJ. Impact of ¹¹C-choline PET/CT scan on detection of recurrent prostate cancer in men with biochemical recurrence following failed initial treatment; supplemented with subject-level data. *J Urol*. 2012; 187:e823.
- ⁷Mitchell C, Kwon E, Lowe V, Hung J, Rangel L, Karnes RJ. Detection of consolidated disease recurrences of prostate cancer by ¹¹C-choline PET/Scan: results confirmed by surgical resection; supplemented with subject-level data. *J Urol*. 2012; 187:e823.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Choline C 11 Injection is packaged in a single dose glass vial containing between 148 MBq/mL to 1,225 MBq/mL (4 mCi/mL to 33.1 mCi/mL) of ¹¹C-choline at EOS calibration time in aqueous 0.9% sodium chloride solution (approximately 10 mL volume).

16.2 Storage and Handling

Store Choline C 11 Injection at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) (see USP Controlled Room Temperature). Use the solution within 120 minutes of EOS calibration.

17 PATIENT COUNSELING INFORMATION

- Instruct patients to drink plenty of water or other fluids (as tolerated) in the four hours before their PET/CT study.
- Instruct patients to void after completion of each image acquisition session and as often as possible for one hour after the PET/CT scan ends.

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