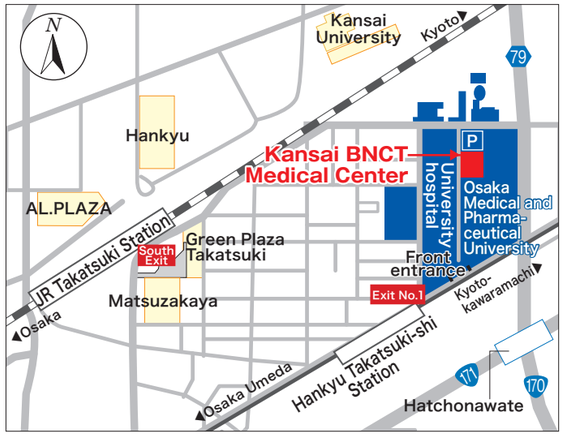
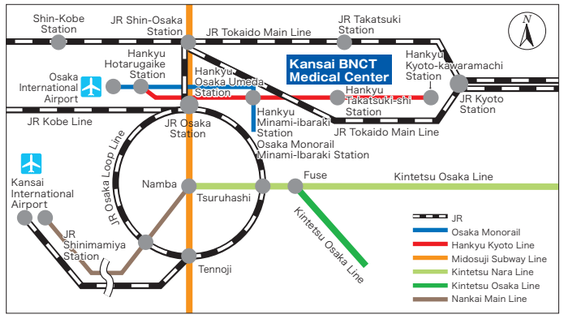
The center, close to both JR Takatsuki and Hankyu Takatsuki-shi stations, is in a “prime location” within 20 minutes of both Osaka and Kyoto cities.





Osaka Medical and Pharmaceutical University

Kansai BNCT Medical Center

2-7 Daigakumachi, Takatsuki, Osaka 569-8686
(inside the premises of Osaka Medical College)
Telephone: 072-683-1221(switchboard)
https://www.osaka-med.ac.jp/kbmc/

Access by Train

- Near Exit No. 1 of Hankyu Kyoto Line "Takatsuki-shi" Station
- 8-minute walk from South Exit of JR Tokaido Main Line (JR Kyoto Line) "Takatsuki" Station
- Free shuttle bus available from JR "Takatsuki" Station

Access by Car

- Right after entering Prefectural Route 79 at Route 171 "Hatchonawate" intersection

※There is multilevel car parking on the premises (Max 200 cars; metered)

Access by Tokaido / Sanyo Shinkansen bullet train

- Alight at "Shin-Osaka" Station and change to JR Tokaido Main Line (JR Kyoto Line) in the direction of Kyoto. Alight at "Takatsuki" Station.
  Travel time: approximately 10 minutes (by special rapid or shin-kaisoku)
- Alight at "Kyoto" Station and change to JR Tokaido Main Line (JR Kyoto Line) in the direction of Kyoto. Alight at "Takatsuki" Station.
  Travel time: approximately 12 minutes (by special rapid or shin-kaisoku)

Access from Osaka International (Itami) Airport

- Take the Osaka Monorail at "Osaka-Airport" Station and alight at "Minami-Ibaraki" Station.
  Change to Hankyu Kyoto Line "Minami-ibaraki" Station towards Kyoto-kawaramachi and get off at "Takatsuki-shi" Station.
  Travel time : approximately 55 minutes

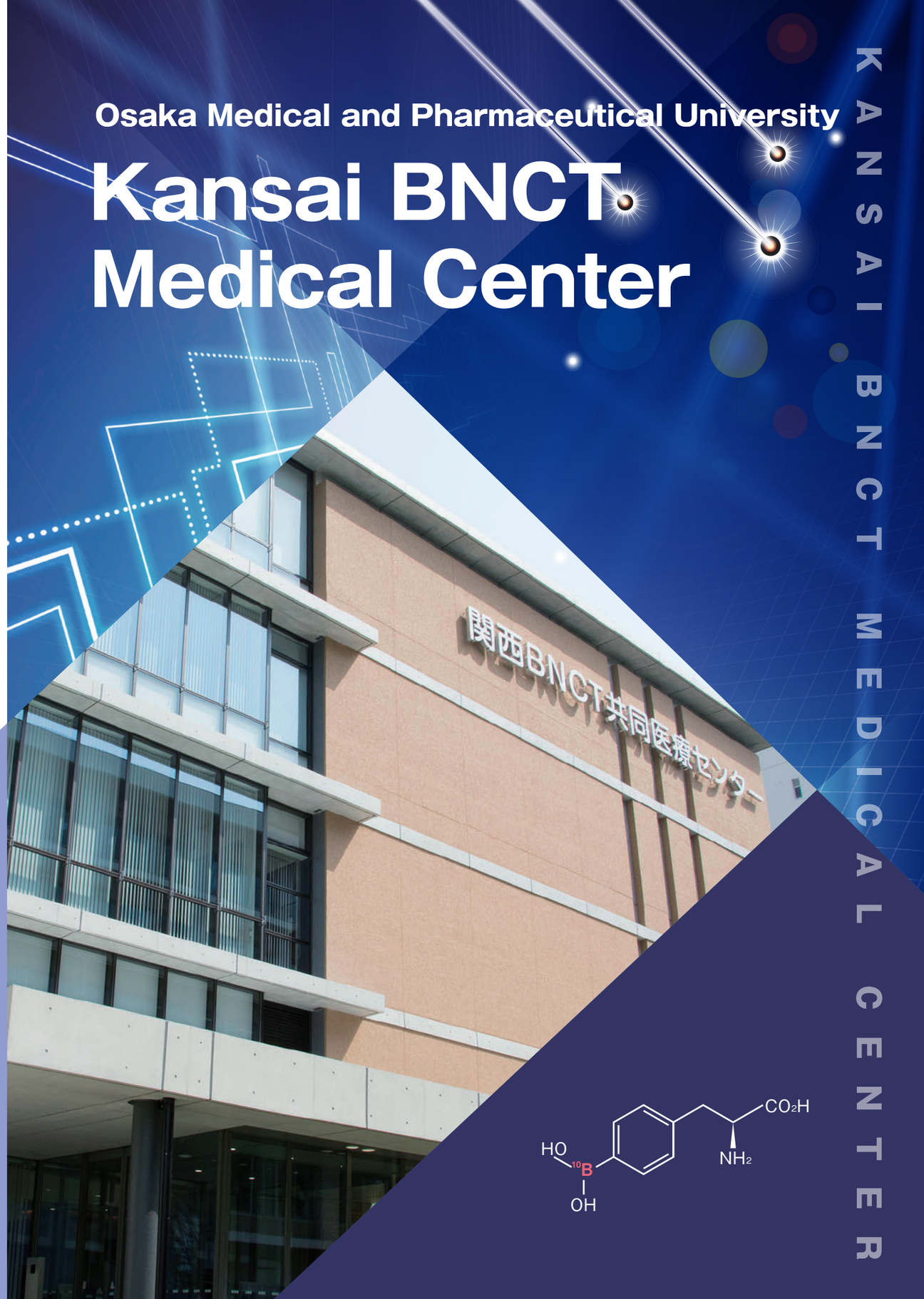
Access from Kansai International Airport

- Change to JR Tokaido Main Line (JR Kyoto Line) in the direction of Kyoto and get off at "Takatsuki" Station.
  Travel time : approximately 90 minutes
- Access by airport limousine bus (to JR Ibaraki Higashiguchi (east exit) via Hankyu Ibaraki Higashiguchi). Alight at "Hankyu Ibaragi Higashiguchi." Change to Hankyu Kyoto Line "Ibaraki-shi" Station towards Kyoto-kawaramachi and alight at “Takatsuki-shi" Station.
  Travel time : approximately 100 minutes

Osaka Medical and Pharmaceutical University

Kansai BNCT Medical Center

KANSAI BNCT MEDICAL CENTER



Minoru Ueki, Chairman of the Board of Directors, Educational Foundation of Osaka Medical and Pharmaceutical University

Having received valuable advice and assistance from many people since the Educational Foundation of Osaka Medical and Pharmaceutical University first embarked on formulating the core concept, Kansai BNCT Medical Center was completed a little over three years later in March 2018. The facility is scheduled to start providing medical care in 2020 as a center for boron neutron capture therapy (BNCT), a new generation of cancer therapy, having undertaken a wide variety of clinical trials aimed at expanding PET-CT operations and the range of cancers amenable to BNCT.

Given the need to improve the QOL of cancer patients, boron neutron capture therapy (BNCT) is a technique that can provide treatment over a short period based on the principle of a single treatment being 30- to 60-minutes, without the need for surgery and with excellent characteristics in terms of the low incidence of side effects.

There are growing expectations for BNCT as a new option for cancer therapy, with potential benefits for cancers that are inoperable or that do not respond to other treatments, being suitable in particular for recurrent cancers after receiving conventional radiotherapy.

The foundation recognized the characteristics of BNCT at an early stage and played a leading role in working toward the practical realization of the technique, including working with the Kyoto University Institute for Integrated Radiation and Nuclear Science to undertake clinical research using a nuclear reactor and being the organization responsible for the clinical trials that are currently in progress. As a result, the college has acquired a level of experience that is high by world standards in terms of the number of brain tumor cases.

With BNCT currently in the incubation stage, making the transition from clinical research through clinical trials to clinical use, the foundation will use the experience it has acquired to date as a basis for directing its efforts at conducting further research at the center in parallel with clinical use, taking advantage of the fact that it is affiliated with the college, with the aims of improving treatment techniques and expanding the range of cancers it can be used to treat.

As the accumulation of research on BNCT in the Kansai region makes it a world leader, with the Kansai BNCT Medical Center acting as a hub for medical research into BNCT in collaboration with relevant institutions and other organizations and taking steps that will enable it to contribute to resolving the medical communities present-day challenge of cancer eradication, I urge you all to continue providing us with your advice and assistance.

Koji Ono, Director of BNCT Clinical Research Institute at Osaka Medical and Pharmacetical University

BNCT utilizes the nuclear reaction between boron atoms (^{10}B) and neutrons to selectively destroy and kill tumor cells from the inside.

Although the idea behind the technique was devised in the USA in 1936 (year 11 of the Showa Era), four years after the discovery of the neutron, it was the work undertaken in Japan, specifically that of the researchers in the Kansai region, that led to its practical application to therapy. Along with medicine and biology, the technologies underlying BNCT cover a wide range of academic fields encompassing engineering (the neutron source) and chemistry (boron-containing drugs). The greatest contribution has been made in the Kansai region in establishing the technique through collaborative work and early establishment of a community of researchers, clinicians and others.

Although the current clinical trials that are in progress utilize boronophenylalanine (BPA) to treat recurrent brain tumor cases and head and neck cancers, the potential for the therapy to be used on a wide variety of different cancers has also been demonstrated, including the clinical research conducted to date at the Kyoto University Institute for Integrated Radiation and Nuclear Science.

With the Kansai BNCT Medical Center at Osaka Medical College currently taking BNCT from the research to the clinical stage, the center was established to serve as a hub for clinical research aimed at improving related techniques and the range of cancers that BNCT can be used to treat based on collaboration with relevant medical institutions and research facilities such as the Kyoto University Institute for Integrated Radiation and Nuclear Science , while also proceeding with clinical deployment using the platform provided by the accumulation of research in the Kansai region.

Compared to other therapies, I believe that BNCT has the potential to demonstrate benefits broadly for a wide variety of cancers, and I am expending my utmost efforts so that the center can become a major hub for BNCT medicine both in name and in reality, can meet the expectations of cancer patients, and can contribute to dramatic advances in cancer therapy. I urge you to extend your understanding and support for this endeavor.

Keiji Nihei, Director of Kansai BNCT Medical Center at Osaka Medical and Pharmacetical University

On April 1, 2020, I was appointed Director of the Kansai BNCT Medical Center. Since August 16, 2019, I have been in charge of Radiation Oncology Department at our university. Until now, I have mainly been engaged in the clinical practice and research of external beam radiation therapy using X-rays and particle beams.

BNCT is a treatment that selectively destroys and kills cancer cells by causing a nuclear reaction between neutrons irradiated from outside and boron absorbed into the cancer cells. Although it can be said to be a type of radiation therapy, it has a different mechanism from conventional external radiation therapy and is an unprecedented, groundbreaking treatment. It has a long history, and for over 30 years, researchers in the Kansai region have led basic research and clinical applications, but in terms of full-scale clinical introduction, it is a new and promising treatment for the future.

After going through research and clinical trials, BNCT finally began to be covered by insurance on June 1, 2020 for unresectable locally advanced or locally recurrent head and neck cancer. In addition to active clinical applications in the future, further leaps are expected from basic research in various related fields. These include research and development of new boron drugs, physics or engineering research on neutron irradiation systems, treatment planning, and dose evaluation, research on qualitative diagnosis and assessment of treatment efficacy using FBPA-PET, and radiobiological research to clarify the effects on normal tissue. One of the major challenges is developing human resources to meet these clinical and research needs.

Kansai BNCT Medical Center is the world's first clinical facility attached to an educational and research institution. In the future, with the cooperation of Osaka Medical and Pharmaceutical University Hospital, we will work together as a team to contribute to the development of cancer treatment, with the three pillars of medical care, research, and the training of human resources for that purpose. We would appreciate your support and cooperation.

Basic philosophy of Kansai BNCT Medical Center

As a specialized facility of BNCT (Boron Neutron Capture Therapy), we provide safe and high-quality medical care in response to the expectations of cancer patients, as well as engaging in the popularization and development of BNCT, including expanding the types of cancer it can treat.

1. As a trusted medical institute
   Respecting the will of each one of our patients, we will continue striving to protect the rights of those consulting with us as well as to provide safe and caring remedies.
2. As a BNCT treatment base facility
   In collaboration with BNCT-related research and medical institutions, we will make efforts to accumulate cancer treatments and form a BNCT medical base.
3. As a college-affiliated facility
   We will promote sound clinical treatment and continuous research for the expansion of BNCT for wide variety of cancers as well as contributing to develop medical professionals supporting BNCT.

Our Projects

1. FDG-PET Examination Project
   Introducing state-of-the-art PET-CT, the center conducts cancer screening for complete medical checkups as well as PET examination for cancer diagnosis.
2. BNCT Treatment Projects
   After obtaining medical approval for BNCT, consultation will be started.
3. BNCT Research and Human Resource Development Project
   We will promote researches to expand BNCT for wide variety of cancers and to improve therapeutic technology, as well as projects to develop human resources supporting BNCT.

Kansai BNCT Medical Center - Facility Profile

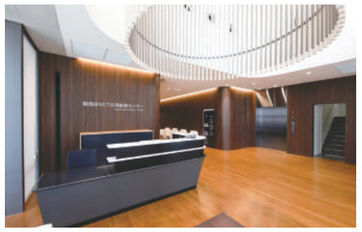
○ Building area : 1,331.01㎡ ○ Total area : 4,028.85㎡ ○ Structure : reinforced concrete
○ Number of floors : 1 floor underground and 3 floors above ground ○ Building height : 19.110m

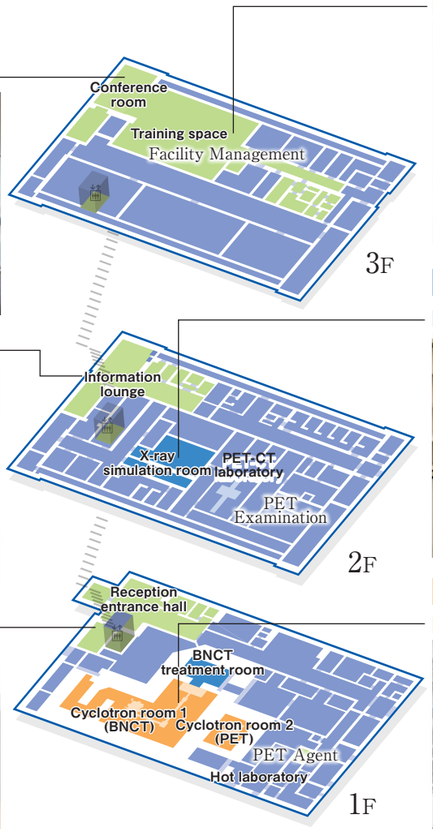
Shared Zone

3F Conference room

2F Information lounge

1F Entrance hall





Shared Zone

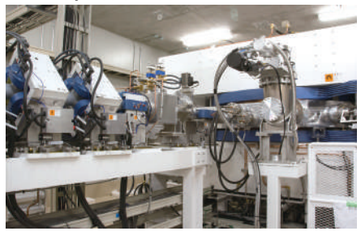
3F Training space

BNCT Equipment Zone

2F X-ray simulation room

BNCT Equipment Zone

1F Cyclotron room 1

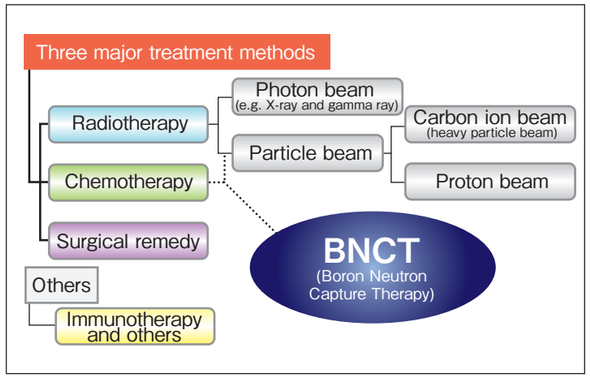


What is BNCT (Boron Neutron Capture Therapy)?

BNCT (Boron Neutron Capture Therapy), utilizing the nuclear reaction between neutrons and boron, is a treatment method that selectively destroys cancer cells without causing damage to normal cells. In addition to primary tumors, the effect can be also expected for cancers that have spread over an individual organ, as well as metastatic and refractory cancers.
Even after conducting regular radiotherapy, BNCT can be expected to be effective for recurrent cancer. It can also be combined with other therapies to further enhance the treatment effect. With this treatment method, which is minimally invasive without incision or resection, an improved QOL (quality of life) for patients can be greatly expected.

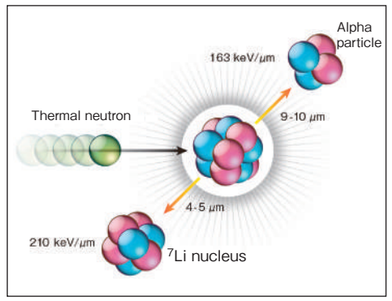
New cancer radiotherapy option BNCT positioning in cancer therapy types

What kind of treatment is BNCT? Cancer treatments are divided roughly into three types: radiotherapy, chemotherapy, and surgery. BNCT takes advantage of the reaction between neutrons and boron atomic nuclei to selectively destroy cancer cells. In terms of effectiveness and safety, it is an epoch-making cancer therapy that is completely different from conventional radiotherapy, and a promising, totally new treatment approach that will support the cancer radiotherapy of the future.

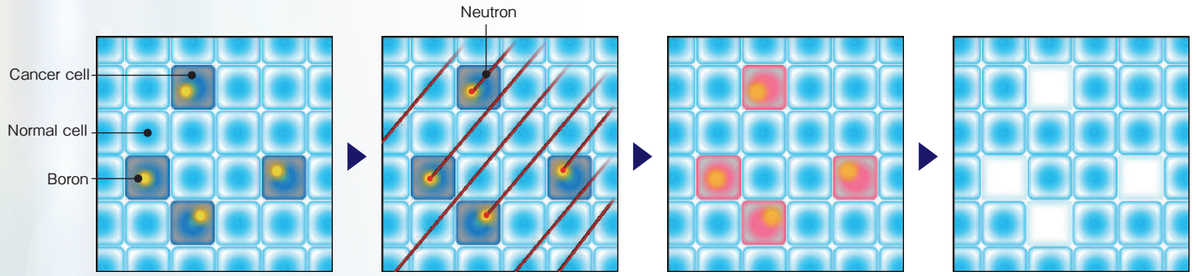


Principles of BNCT (Boron Neutron Capture Therapy)

- Boron Neutron Capture Therapy (BNCT) is a treatment that destroys cancer cells by nuclear reaction of boron and neutrons.
- Pre-administered boron compounds are selectively accumulated in cancer cells. By irradiation with neutrons, alpha particle and lithium nucleus are generated from boron nucleus, which destroy cancer cells.
- Since the range of released particles is almost equivalent to the cell diameter, cancer cells that take up boron compounds can be selectively destroyed from the inside. Thus, cancer cells can be killed without damaging surrounding normal tissues.
- Therefore, effects can be expected not only for primary tumors, but also for cancers that have spread throughout organs, metastatic cancers, and refractory cancers. Patients can be treated even after receiving regular radiotherapy, so the therapy is greatly anticipated to treat recurrent cancer.



Source:Pioneered by Japanese Brainpower:New Horizons in Cancer Treatment (Boron Neutron Capture Therapy)



1)Before commencing BNCT, boron compounds are administered intravenously. The boron compounds are taken up into cancer cells.
2)Epithermal neutrons are externally irradiated to the affected area.
3)Radiation is generated in the cancer cells by nuclear reaction of boron and neutron.
4)The cancer cell with accumulated boron compound is selectively destroyed.

Advantages of BNCT (Boron Neutron Capture Therapy)

1. Substantially less damage to normal cells compared to regular radiotherapies
2. Available for application to recurrent cancer after radiotherapy
3. Expected to be effective on invasive, multiple, and radiation-resistant cancers
4. Short treatment period (completed with one or two irradiations, about 30 to 60 minutes per irradiation)
5. Predictable treatment effect using PET examination

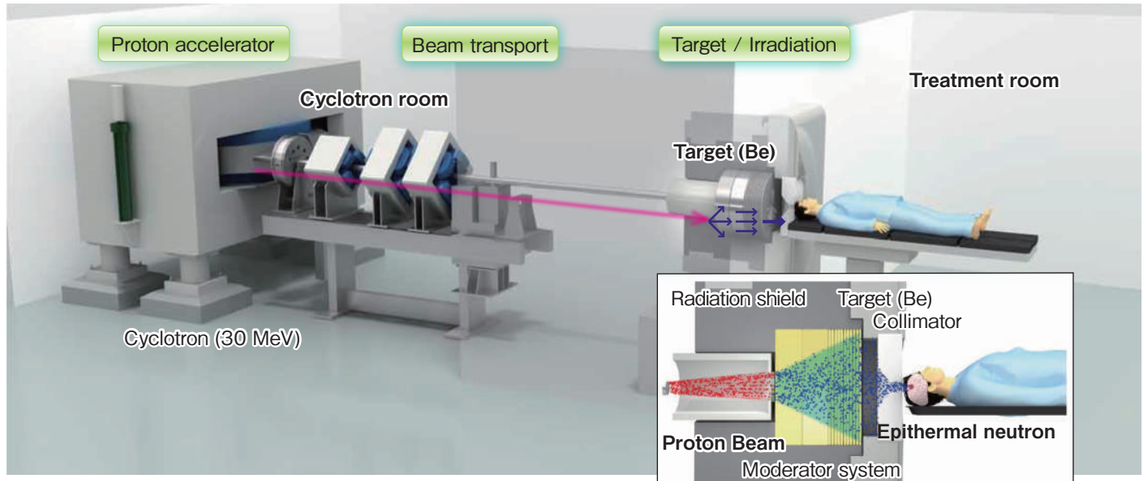
Target diseases for BNCT

Diseases tested from clinical trials
- Brain tumors
- Head and neck cancers
- Malignant melanoma
- Lung cancer / pleural mesothelioma
- Liver cancer
- Breast cancer and others

Target diseases for ongoing clinical trials
- Recurrent malignant glioma
- Head and neck cancer

Image of the accelerator-based neutron irradiation system

Accelerator BNCT system (C-BENS)



Sumitomo Heavy Industries,Ltd.

BNCT (Boron Neutron Capture Therapy) Procedures

1 Study based on a preplan

A preplan is generated using CT images taken in advance to determine whether or not sufficient neutrons can be irradiated to the target area.

Treatment planning system

2 Prediction of treatment effect using FBPA-PET
(Not covered by Japanese National Health Insurance)

PET examination using FBPA (labeling boron compound BPA with ^{18}F) is conducted prior to treatment to check the BPA accumulation level and determine if the treatment is feasible.

PET/CT Scanner

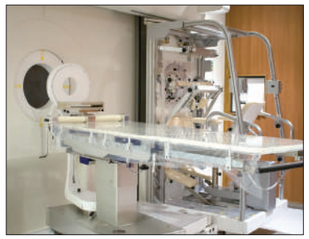
3 Simulation/Treatment planning
(Patient positioning, CTscan, dose calculation)

After considering the posture and position during irradiation, CT scans are taken in the actual treatment position, and the images are used to create a final treatment plan.

CT Scanner

4 BNCT treatment
(irradiation)

On the day of treatment, BPA is administered to the patient and neutrons are irradiated to the target area.



BNCT treatment room

PET Examination

PET, which stands for Positron Emission Tomography, is a type of nuclear medicine imaging that can examine the whole body in a single procedure.
In a PET examination, radioactive compounds are internally administered to image its distribution by camera.
PET has been used to diagnose tumor size and location as well as metastasis and recurrence of cancer. Being useful for the early detection of cancer, PET is also used for screening.

PET-CT

PET-CT is an integrated equipment consisting of PET, which images the activity of cancer cells, and CT, which projects the shape of organs. It displays the organ and location of cancer and other information that have been projected by PET, enabling accurate diagnosis of cancer.

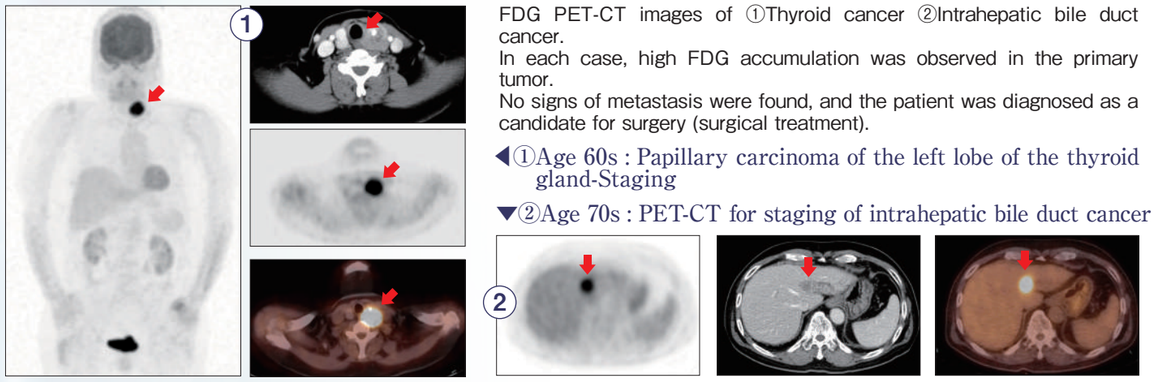
FDG-PET (Covered by Japanese National Health Insurance)

Kansai BNCT Medical Center conducts examination using a radioactive compound called FDG.

Health insurance coverage of FDG-PET examination (※as of April 2018)

Malignant tumors ※ Excluding early gastric cancer	Those who cannot receive a definite diagnosis of staging, metastasis, or recurrence by other examinations or diagnostic imaging
Epilepsy	Those in need of surgery with intractable partial epilepsy
Heart disease	Viability diagnosis of myocardial tissue in patients with heart failure due to ischemic heart disease (only in cases where diagnosis cannot be made by other examinations); or, for patients in need of diagnosis of inflamed area in cardiac sarcoidosis.
Large-vessel vasculitis (Takayasu arteritis or giant cell arteritis)	Those who already have a diagnosis of large-vessel vasculitis, but the localization or activity of the lesion cannot be determined by other examinations

Imaging of abnormal findings by [^{18}F]FDG PET-CT examination (example)



FDG PET-CT images of ①Thyroid cancer ②Intrahepatic bile duct cancer.
In each case, high FDG accumulation was observed in the primary tumor.
No signs of metastasis were found, and the patient was diagnosed as a candidate for surgery (surgical treatment).

◀①Age 60s : Papillary carcinoma of the left lobe of the thyroid gland-Staging

▼②Age 70s : PET-CT for staging of intrahepatic bile duct cancer

FBPA-PET (PET agent for BNCT)

Kansai BNCT Medical Center has been engaging in research to diagnose BNCT indication by imaging the accumulation state of boron compound BPA in cancer for BNCT.

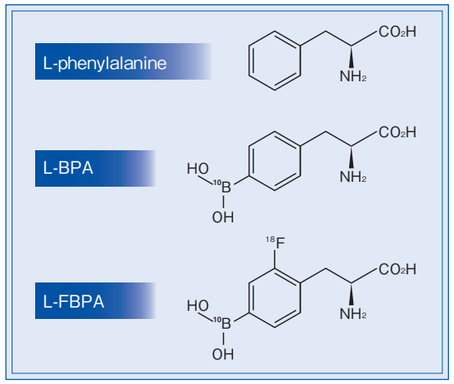
▶ Nuclear medicine imaging by FBPA-PET

FBPA is a radioactive compound for PET, labeling boron compound BPA for BNCT with radioactive substance ^{18}F. PET examination using FBPA can obtain the following images:

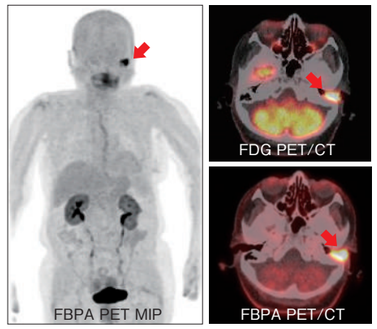
- How much BPA will be taken up in a tumor?
- Location and range of tumor

In cancer treatment, distinguishing cancer and general inflammation is also important. The agent FBPA is easily accumulated in inflammation sites, thus it is excellent for distinguishing cancer and inflammation. In order to expand BNCT for wide variety of cancer types in the future, FBPA-PET examination will play an important role.

- Phenylalanine, a type of amino acid, is often taken into actively proliferating cancer cells.
- Boronophenylalanine (BPA), or phenylalanine labeled with boron (^{10}B), is used as a boron compound for BNCT. Since phenylalanine is labeled with boron, it carries a considerable amount of boron to the cancer tissue.
- PET examination generates an image of BPA uptake in cancer tissue using FBPA, or BPA labeled with radioactive nuclide ^{18}F.



Imaging of abnormal findings by [^{18}F]FBPA PET-CT examination(example)



Three years ago, the patient was diagnosed with left external auditory canal cancer (squamous cell carcinoma) and underwent surgical resection. Subsequently, a mass reappeared at the treatment site, and an FDG-PET scan showed high FDG accumulation in the recurrent mass,and a biopsy revealed a pathological diagnosis of local recurrence.
An FBPA-PET scan also showed high FBPA accumulation in the recurrent mass, with the level of accumulation being approximately 7 times higher than in the surrounding normal areas,
and the patient was diagnosed as a suitable candidate for BNCT.

◀Age 80s : case of recurrence of external auditory canal cancer

Hot laboratory

PET waiting room