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| Protocol Title:  Chinese:  English: (not mandatory, fill in according to trial conditions) | |
| Trial Institution: XX Department of OO Hospital | Sponsor/Pharmaceutical Company for this Trial: OO Company or OO Hospital  Source of Research Funding: |
| Principal Investigator: Dr. OOO  Sub-Investigator: Dr. OOO | Title: XXX Chief/Attending Physician  Title: XXX Chief/Attending Physician |
| 24-hour emergency contact person: | Doctor OOO, Research Nurse XXX Telephone No.: |
| Subject name: | Medical Record No.: |
| You are being invited to participate in this clinical trial. This form provides information related to this trial. The principal investigator or his/her authorized staff will explain the content of this trial to you and answer any questions you may have. Please do not sign this consent form until all of your questions have been answered satisfactorily. You do not have to decide whether you will take part in this trial right away. Please consider carefully before you sign your name. You must sign the consent form to participate in this trial. If you are willing to participate in this trial, this document will be considered as the record of your consent. You can withdraw from the trial at any time without any reason, even after you have given consent. | |
| (I) Trial objective:  This trial is a Phase X (multinational/Taiwan single center/Taiwan multicenter) clinical trial. XX subjects are expected to be recruited globally, including XX subjects from Taiwan. The objective of this trial is to assess the treatment efficacy of OO disease, or to understand the safety of long-term use. (fill in as appropriate)  **This trial is the first time (drug name) is used in the human body.** (if this point is valid, please fill in using bold text)  All treatments bear risk, and this clinical trial is not an exception. Please consider carefully before deciding whether to participate in this trial. | |
| (II) Current status of the investigational drug:   1. Information of this product: drug name, brief mechanism of action, route of administration, research and develop indications, current research and development period and usage experience (for example, number of users). The indications which are not included in this study may also be explained. 2. Marketing status of this product: Not marketed globally or approved countries, approved indications; current marketing status in Taiwan)   The efficacy of (drug name) used in this study has not been confirmed in the treatment of your disease. | |
| (III) Main inclusion and exclusion criteria of the trial:  The physicians or relevant researchers of OO Hospital who perform this research study will discuss with you the necessary conditions for participation in this research. Please cooperate with us and be honest with us about your past health condition. If you do not meet the requirements of this research, you may not be allowed to participate in this research study.  Requirements for participation in the research study:   * You must be over OO years old * You must not have donated more than 500 cc of blood within 3 months * You must return for follow-up visits at scheduled times during 26 months of this study.   You will not be allowed to participate in this research study if you fulfill any of the following conditions:   * You have participated in another study within 1 month * You are a drug and alcohol abuser | |
| (IV) Methods and related procedures of this trial  If you have decided to participate in this research study and signed the consent form, you will undergo physical examination, including blood and urine tests, height and body weight measurement, heart rate and blood pressure measurement, as well as hip bone density test. The hip bone density test is non-invasive with the radiation amount equivalent to chest X rays. If you meet the requirements, you will start taking calcium tablets and vitamin D orally once per day, as well as injections of investigational product\_\_\_ or placebo.  To ensure that the results are not distorted, the study is designed to be a randomized double-blind research. Half of the subjects are given the investigational product\_\_\_, and the other half is given “placebo”. The "placebo" is a drug that has the same appearance as the investigational drug but does not contain the active ingredient. The decision on who will get the investigational product, and who will get the placebo is decided by chance, like flipping a coin or throwing a dice, and both you and your trial physician do not know which drug you have taken. This is called double blind.  Investigational drug  , solution for injection, containing 100 mg of \_\_\_\_\_\_\_\_(10 mL) per vial.  Trial procedure  Screening period ( Day -7 to Day -1)  Within the first week of the first treatment period, the trial staff will explain the content of the trial to you and ask you to sign the Informed Consent Form. If you agree to participate in this trial, the trial staff must obtain the following information and assessment results:  ………….(omitted)  Treatment period (first cycle) -Day 8 (±3 days) and Day 15 (-3 to+7)  During this visit period, you should undergo the following procedures:  ………….(omitted)  Trial Procedure Table or Flowchart (at your discretion): All the possible procedures are shown in the left column of the table, and the time when these procedures will be performed is indicated in other columns | |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Procedures | Screening period | | Double-blind period | Final visit or early termination visit | Follow-up visit | | Screening visit #1 | Screening visit #2 | A total of 26 monthly visits (interval of 28 days between visits) | 28 days after the last dose | 85 and 169 days after the last dose | | Sign the Informed Consent Form | 🗸 |  |  |  |  | | Medical history | 🗸 |  |  |  |  | | Inspection of medications | 🗸 | 🗸 | All visits except visits on Day 344 and Day 351 | 🗸 | 🗸 | | Inspection of side effects | 🗸 | 🗸 | All visits except visits on Day 344 and Day 351 | 🗸 | 🗸 | | Blood sample | 🗸 | 🗸 | All visits | 🗸 | 🗸 | | |
| (V) Possible risks and their incidence and countermeasures:  1. Risks associated with the investigational drug (side effects of the drug used in this trial)  All investigational drugs may cause side effects, and you may or may not experience the following side effects.  Side effects:  Side Effect A (indicate the incidence rate of this side effect)  Side Effect B (indicate the incidence rate of this side effect)  Observed serious side effects and their countermeasures:  There might be other side effects associated with this trial that are currently unknown. During the trial, the trial physician and other trial staff will regularly monitor your side effects. When necessary, you will be arranged for additional visits and tests. If you experience any side effects, please inform your trial physician and other trial staff so that the trial physician can decide on the appropriate treatment for your case.  2. Risks associated with the trial process  During the trial, you may feel discomfort, and certain tests may be dangerous, such as blood collection, ECG, liver biopsy, etc.   * Blood sample collection: Blood sample collection from the arm may cause pain, bruising, dizziness, and very rarely, even infection. Countermeasures include: pressure at blood draw site for at least 5 minutes after blood collection; bruising can be eased by hot compress; for dizziness, you should sit or lay down for rest. If you have developed an infection at the blood draw site, please contact the research investigator immediately and Hospital will provide you with necessary medical care. * Blood drawing on an empty stomach may cause dizziness, headache, stomachache or fainting. The treatment is sitting down to rest and eating as soon as possible after the blood draw. * The electrode patches for ECG may cause redness or itching of the skin and can cause mild discomfort. No treatment is required. * Liver biopsy related risks include abdominal bleeding, liver hematoma, hepatic duct hemorrhage, bacteremia, biliary peritonitis, pleuritis, or harm to adjacent organs, with incidence rate of 0.06% to 0.32%, in the worst case may lead to death, but the chance is less than 1/ 10000 to 1/12000. The medical staff will monitor you at any time after the examination in order to provide immediate treatment if necessary.   If you experience any of these serious or dangerous side effects, you should take the following actions as soon as possible:  1. Call the 24-hour emergency contact person as soon as possible.  2. Go to the nearest emergency room if necessary. | |
| (VI) Alternative treatments and explanations  Example 1:  You do not have to participate in this trial in order to improve your disease condition. If you do not participate in this trial, there are other treatment options for you, including approved or commercial drugs, surgical procedures, or other experimental drugs. Your trial physician can discuss the risks and benefits of these alternative treatment options with you. In addition, you can discuss your options with your primary care physician.  Example 2:  You are not obliged to participate. If you do not participate in this research, you can receive routine treatment or other possible treatments including drug treatments or / and surgery, and past experience of the study drug usage in humans indicates that .  Example 3:  No other alternative treatments are available. At present, for disease, the routine treatment is limited to slightly postponing the time of death. The disease cannot be treated. | |
| (VII) Anticipated trial benefits:  Example 1: (experience of the drug use in human body is available):  Past experience of the drug use in human body indicates that .  Even with the above information, participating in this trial does not guarantee any improvement of your disease or bring you any other direct benefits. However, the trial research results may be helpful to the Sponsor and/or Principal Investigator and may also benefit other patients with the same disease in the future.  Example 2: (experience of the drug use in human body is not available):  The (study) drug has not yet been tested in humans, but according to the reaction observed in animal studies, the study drug is likely to \_\_\_\_\_\_.  Even with the above information, participating in this trial does not guarantee improvement of your disease or bring you any other direct benefits. However, the trial research results may be helpful to the Sponsor and/or Principal Investigator and may also benefit other patients with the same disease in the future. | |
| (VIII) Contraindications, restrictions and rules that must be abided by during the trial:  During the trial period, for your safety, we need your cooperation in the following matters:  -You should not participate in any other clinical research.  -Provide correct information on your past medical history, medical records, and current medical condition.  -Use the study drug as instructed.  -Do not give the study drug to other people. Keep the study drug in (method of storage: room temperature, refrigerated, etc.) and make sure children do not have access to it.  -Return the unused study drug and empty packaging of the tablet to us. (according to the trial protocol)  -For your safety, please return to the hospital for scheduled visits. If you are not able to come as scheduled, please contact the trial staff.  -Please fill out the diary timely to record your condition. (according to the trial protocol)  -For your safety, please inform the trial physician of any discomfort that you may experience.  -Do not take other medications, including over-the-counter drugs, Chinese medicine and health supplements. If you need to use other medications, please discuss it with your trial physician. (according to the trial protocol)  -Information on medications (e.g. whether medications should be taken before or after meals, time of administration, prohibited drugs, and drug interactions, etc.) (examples can be provided, such as CYP Inhibitor and Inducer, etc.) (according to the trial protocol)  -If other physicians prescribe a new drug or change current medications, even the disease is irrelevant to the study drug, please inform your trial physician.  -If you have any questions, feel free to ask your trial staff (physician or nurse) directly.  -Please do not get pregnant or get someone pregnant. If it is still possible for you to get pregnant or get someone pregnant, please use an effective contraceptive method during the trial period, for example, intrauterine devices or hormonal contraceptives. (according to the trial protocol)  -Animal trials have indicated that the study drug will affect fertility. Animal trials have suggested that the study drug can cause abnormal growth and development of the fetus during the treatment period. (it depends on whether data on reproductive toxicity or teratogenicity is available)  -Please carry the patient card with you at all times. This card contains the trial information. You need to show this card to all medical staff, including the staff of other hospitals, to let them know that you are participating in this trial. (if applicable)  -If you are being treated in other hospitals or clinics, please tell their medical staff that you are using certain study drug.  -If you are hospitalized or your medical condition has changed between two visits, or you would like to discontinue the use of the study drug (or have discontinued taking the drug), please inform your trial physician of the situation. | |
| (IX) Confidentiality of subject's personal information：  OO Hospital will abide by the law to keep the confidentiality of any record containing your identification and your personal private information, and will not disclose it. The research staff will assign you with a research code, and this code will not show any identifiable information such as your name, identification number or address. In the event that trial results are published, your identification will continue to be kept confidential. You also understand that by signing this consent form, you are approving direct use of your original medical records by the monitors, auditors, (the name of the hospital IRB) and the competent authorities, in order to ensure that the clinical trial is conducted and data are collected in accordance with applicable laws and regulations. The aforementioned personnel guarantee the confidentiality of your identity will not be violated. Except the aforementioned authority’s inspection as required by law, we will carefully protect your privacy. Because the study drug is being tested simultaneously in the US and the EU, according to the US and EU regulations for the management of medicinal products, the trial results will be published on the website: Clinicaltrials.gov (US) and clinicaltrialsregister.eu (EU), but your personal information will remain confidential as only the abstract of the trial results will be public on the website. In addition, you can search the website at any time.  Because this trial needs to exclude those infected with human immunodeficiency virus (HIV), you will receive the human immunodeficiency virus (HIV) test. You can participate in this trial only if your test result is negative. If your test result is positive (including false positive), The trial hospital and trial physician will provide you with subsequent medical referral or consultation and will report to the competent authority as required by the law. | |
| (X) Withdrawal and termination of the trial  You are free to decide whether to take part in this trial. During the trial, you can withdraw your consent and leave the trial at any time, without giving any reason, and no unpleasantness will be caused, nor will your medical care from your physician be affected. How to withdraw from the trial (revoking your consent): notifying the contact person/research nurse by phone… For your safety, you must withdraw from the trial in case of the following conditions:  (please list all conditions for withdrawal)  During the course of the trial, you will be informed of important new information (i.e. information relating to your rights/benefits or that will affect your willingness to continue taking part in this trial/research), and provided you with further explanation. Please consider whether to continue taking part in the trial. You are free to make a decision and this decision will not cause any unpleasantness or affect your future medical care.  It is also possible that the Principal Investigator or the Trial Sponsor will terminate the clinical trial or your participation in the trial whenever necessary.  If you decide to withdraw from the trial, or if the Principal Investigator decides to terminate your participation in this trial, the data collected before your withdrawal will be preserved, and will not be deleted. After withdrawal, you may decide the handling method of the samples you previously provided, and decide whether to give consent to allow the Principal Investigator or Trial Sponsor to continue collecting your data.  1. For the samples that I have previously provided (choose one),  □ I give my consent to authorize the trial to continue using the samples for research related to the trial disease. Another consent from me should be obtained if the scope of use exceeds this original informed written consent.  □ I do not give my consent to authorize the trial to continue using the samples. However, to ensure the accuracy of the completed tests, I agree to allow the laboratory to destroy the trial-related samples after re-verification.  □ I do not give my consent to authorize the trial to continue using the samples. Please destroy my trial-related samples on the day of my withdrawal.  2. The Principal Investigator or Trial Sponsor is authorized to continue collecting my data, e.g. accessing my medical records to obtain the follow-up medical procedures and lab test results. During the period of continuous data collection, your privacy and personal information will remain confidential. (choose one)  □I consent to collection  □I do not consent to continuous collection or inspection of my data. | |
| (XI) Compensation and insurance:  All clinical trials have risks. To ensure the protection you may receive for damages resulting from the adverse events of participating in this trial, please be sure to read the content of this section:   1. OOO Company or OO Hospital or OO Company and OO Hospital will bear liabilities for compensation of damages caused by the adverse events resulting from following the protocol designed for this clinical trial (please refer to the Appendix Compensation Explanations for details, e.g. insurance policy and /or guidelines for compensation of the hospital). However, no compensation will be made with respect to the expected adverse events described in this Informed Consent Form. 2. The hospital will provide professional medical care and consultations for adverse events or damages resulting from following the protocol designed for this clinical trial. You will not be responsible for the necessary medical expenses with respect to the treatment for the adverse events or damages. 3. This trial does not provide compensation in any form other than the compensation and the medical care set forth in above 2 points. If you do not accept this level of risk, please do not participate in the trial. 4. You will not lose any legal rights pursuant to your signing of this Informed Consent Form. 5. This trial is (or is not) insured against human research liability. (Note: The sponsor and trial institution can decide whether to specify matters related to insurance.)   If the damages are caused by the adverse events resulting from your participation in the trial, the compensation mentioned above includes reasonable medical expenses. However, the following requirements must be met: you follow the instructions given by your trial physician on using the study drug; your damage is not caused intentionally; you obey the medical recommendations given by your trial physician. | |
| (XII) Storage, use and reuse of subject's samples (including their derivatives) and personal information  1. Storage and Use of Samples and Residual Samples  (1) Storage and use of samples (including their derivatives)  For the research, your samples collected by us will be used as indicated in the trial protocol and be stored in (unit or lab; if the sample will be delivered to a foreign laboratory, please describe in detail the country, city, place and name of the institution where the lab is located). We will store your samples until year \_\_\_\_\_, and we will destroy the samples in accordance with laws and regulations when the expiration date is due. To protect your privacy, we will replace your name and relevant personal information with a trial code in order to ensure your samples and relevant information are completely confidential. If you have any concerns about the use of the samples or you have any need to destroy the samples, please contact us immediately (Contact person:\_\_\_\_\_\_\_Tel: ), and we will destroy your samples. You can also contact \_\_\_\_ (the name of the IRB of the hospital) (Tel: (XX) XXXX-XXXX ext. XXXX) to help you resolve any disputes over the use of samples for research.  (2) Reuse of residual samples (including their derivatives)  Your biological samples will be coded with a specified code and be stored for up to XX years under the control and management of XX company (Trial Sponsor).  (The following short paragraph is moved from the end of paragraph XII to the current position. Words and sentences have been changed as well.)  All new research studies need to be reviewed and approved by the Institutional Review Board of . If the Institutional Review Board determines that the new research has exceeded the scope of your consent, we will be required to obtain your consent again.  Do you give consent to retain your residual samples for future use in research on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ , and authorize the \_\_\_\_\_\_\_\_ Institutional Review Board to review and determine whether your additional consent is required? (Choose one):  □ I do not consent to having my residual samples preserved. Please destroy them after the trial is completed.  □ I give consent to the preservation of my residual samples by not de-linking. Another consent from me is required before my samples can be used to conduct new research if the usage has exceeded the scope of use.  2. Certain types of samples and residual samples (The types of samples may be added or deleted to reflect the contents of the Protocol.)  (1) Samples for general biochemistry and blood tests  During the trial period, your samples will be delivered to the central laboratory \_\_\_\_\_\_ delegated by XX company (Trial Sponsor) for analysis. The address of the institution is . The central lab will provide the results to the trial center immediately after the analysis is completed. If there are residual samples they will be stored for one week, and destroyed after re-testing of the trial results is completed; they will not be stored for a long period of time.  (2) Samples for pharmacokinetics  During the trial period, your samples will be delivered to the central laboratory delegated by XX company (Trial Sponsor) for handling, processing and further analysis. The address of the institution is . The analysis results will not be provided to the trial center. After the completion of the trial, residual samples, if available, will be stored until the clinical trial report is completed, up to a maximum of 20 years.  (3) Samples for biomarkers/genetics  During the trial period, your samples will be delivered to the central laboratory \_\_\_\_\_ delegated by XX company (Trial Sponsor) for handling, processing and further analysis. The address of the institution is . The central lab will/will not provide the lab test results to the trial center after the analysis is completed. After trial completion, if there are residual samples, these will be stored at \_\_\_\_ for up to a maximum of 20 years.  （4） Samples for exploratory biomarkers/genetics  During the trial period, your samples will be delivered to the central laboratory \_\_\_\_ delegated by XX company (Trial Sponsor) for handling, processing and further analysis. The address of the institution is \_\_\_\_\_\_. The samples for exploratory biomarkers/exploratory genetics will be analyzed in the central lab, and the results will/will not be provided to the trial institution after the analysis is completed. Some exploratory samples will be analyzed after the main study is completed. If there are residual samples/unanalyzed samples after completion of the main study, these samples will be stored by for up to a maximum of 20 years, calculated from the end of the main study.  3. Personal Information  During the trial period, we will collect related data and information about you from your medical charts, medical records, scales, and questionnaires; and provide a study code to replace your name and relevant personal information, depending on the nature of the trial and content of your authorization. If the above-mentioned data and information are in hard copy, they will be kept in a locked cabinet at the trial institution, separated from the Informed Consent Form. Electronic copies or archives for statistics and analysis purposes will be kept in dedicated computers protected by passwords and appropriate anti-virus software (details about storage and management of paper-based and electronic data in this paragraph are only examples, and may be supplemented and corrected to reflect the actual circumstances of respective studies.) All data and information will be stored for at least two years after the drug is listed on the domestic market. If research and development of the study drug is terminated, the data will be stored for a minimum of two years after the discontinuation of the trial. All data and information will be stored for a maximum of \_\_\_\_\_ years after marketing of the drug or official discontinuation of the trial. All information and data will be destroyed afterwards. If the above-mentioned data and information are sent overseas for statistical analysis, you will still be protected at an equivalent level to that under the laws and regulations in your country. The Principal Investigator and the related teams will, in their best effort, ensure that your personal information is properly protected.  4. Genetics test results  Please fill in one of the following sections based on the trial condition  Example 1: If the gene tests show new information, would you like to be notified:  □ notification required □notification is not required  Example 2: The results of gene test will not be disclosed to individual patient. | |
| (XIII) Rights and interests of the subject:   1. During the trial, if you have any questions about the nature of the trial or any concerns about your rights as a patient, or suspect that you have suffered injury as a result of participating in this research, please contact the (name of hospital IRB) to request for consultation. The telephone number is 00-12345678 ext. 0000, 0000. 2. During the trial, any significant findings that are related to your health or the disease and may affect your willingness to continue participating in the clinical trial will be provided to you in a timely manner. If you decide to withdraw, the physician will make arrangements for you so that you will continue to receive medical care. If you decide to continue participating in the trial, you may need to sign an updated version of the Consent Form. 3. You will receive care by Dr. \_\_\_\_\_\_ during the course of the clinical trial. If you have any questions or conditions now, or during the clinical trial, please do not hesitate to contact Dr. \_\_\_\_ at the \_\_\_\_\_\_\_ Division of \_\_\_\_\_\_\_\_\_ Department (24-hr contact number: \_\_\_\_\_\_\_\_\_\_). 4. This consent form is made in duplicate. The Principal Investigator or authorized staff has given you 1 copy of the signed consent form and has fully explained the nature and purpose of this research. The physician has answered all your questions about the drug and research. 5. Reimbursement for participating in the trial research. (Transportation or nutrition fee will be provided at NTD XXX for each scheduled visit or provided to you in separate payments in proportion to the progress of the Protocol.) 6. If any unintended events occur OO years after the end of this trial which can directly affect your safety concern, you will be notified. | |
| (XIV) Anticipated commercial benefit(s) derived from the trial:  Example 1:  The data obtained from this trial may lead to the discovery, invention or development of commercial products, and all the rights belong to the Trial Sponsor. You and your family will not receive any financial benefits or monetary compensation for the research results, discovery or other findings derived from the data, or be granted with the ownership of the aforementioned invention.  Example 2:  The data obtained from this trial may lead to the discovery, invention or development of commercial products. You and your family may receive financial benefits or monetary compensation or be granted with the ownership of the aforementioned invention resulting from the research results, discovery or other findings of the data.  Example 3:  This research is not expected to derive any patents or other commercial interests. | |
| (XV) Signature:   1. The Principal Investigator/Sub-investigator or his/her authorized personnel has explained in detail the nature and objectives of the above research method in this protocol, as well as the possible risks and benefits.   Signature of Principal Investigator/Sub-investigator:  Date: (Month) (Day), (Year)  Other research staff participating in the consenting process, including discussion and explanation:  Date: (Month) (Day), (Year)   1. I fully understand the research method mentioned above and the possible risks and benefits after the explanation, and my questions about the clinical trial have been answered in full detail. I agree to participate in this research voluntarily and will hold a duplicate of the Informed Consent Form.  |  |  |  | | --- | --- | --- | | Signature of the Subject | Date: (Month) (Day), \_\_\_\_\_\_ (Year) | | | Date of Birth: (Month) (Day), \_\_\_\_\_\_ (Year) | | Telephone No.: | | National ID Number: | | Gender: | | Correspondence Address: | |  | | Signature of the Legal Representative, Person who Has Right to Give Consent: | Date: (Month) (Day), \_\_\_\_ (Year) | | | Relationship with the Subject: |  | | | Date of Birth: (Month) (Day), \_\_\_\_\_\_ (Year)  National ID Number:  Correspondence Address: | Telephone No.: | |   \*For those that the proviso of paragraph 1 of Article 79 of the Medical Care Act or the proviso of paragraph 1 of Article 12 of the Human Subjects Research Act applies to, exercising their right to give consent should be in accordance with paragraph 2 of Article 79 of the Medical Care Act, Article 5 of the Regulations on Human Trials, or paragraphs 3 and 4 of Article12 of the Human Subjects Research Act.  Signature of the Witness: Date: (Month) (Day), \_\_\_\_ (Year)  \* In the event that none of the subject, legal representative or the person who has right to give consent can read, a witness shall be present during every discussion of subject’s consent. The witness shall confirm that the consent given by the subject, legal representative or person who has right to give consent is of voluntary nature before signing and dating the Informed Consent Form. The trial staff shall not be a witness. | |