Clinical study on evaluation of antibiotic application of Anerning granules based on children's community-acquired pneumonia

Informed consent form • notification page

Dear parents of children (legal agent)：

Your child's doctor has confirmed that your child has a child's community-acquired pneumonia wind-heat closed lung syndrome or phlegm-heat closed lung syndrome.

We invite your child to participate in a medical study on the treatment of children's community-acquired pneumonia (wind-heat closed lung syndrome or phlegm-heat closed lung syndrome) with integrated Chinese and Western medicine to evaluate the treatment of Anerning granules combined with ceftriaxone sodium (rochefen) The effectiveness and safety of children's community-acquired pneumonia (wind-heat closed lung syndrome or phlegm-heat closed lung syndrome).

Before you decide whether to participate in this study, please read the following carefully, it can help you understand the study and its significance, procedures and deadlines, understand the benefits and risks that may come to your child after participating in the study. Please read this subject instructions carefully, if you have any questions, please promptly ask, your child's doctor will answer for you. If you want, you can also discuss with your relatives and friends to help you make a decision.The following is an introduction to this study:

1.Research background and research purpose

Anerning Granules is a modern Tibetan medicine preparation produced by Jinhe Tibetan Medicine Co., Ltd. (Z20025878). The prescription was originally derived from the classic prescription "Sanchen San" of Tibetan medicine, which has been continuously improved and perfected by later generations of physicians, forming the classic prescription of pediatrics of

Tibetan medicine "Nine West is better". It is currently published in "Tibetan Medicine Clinical Notes" by Yundan Jiacuo, a well-known Tibetan medical scientist, and has been in clinical use for more than 300 years. The medicine is composed of safflower, sandalwood, tianzhu yellow, artificial bezoar, short-tube rabbit ear grass, rock cabbage, alpine horseradish, aconite, and licorice with the function of clearing heat and removing wind, phlegm, and cough. It is clinically applied to children with wind, heat, cold, cough and phlegm, fever and sore throat, and upper respiratory tract infections.

The purpose of this study was to evaluate the use of An Er Ning granules to reduce the use of antibiotics in children's community-acquired pneumonia, and to evaluate the synergistic effect of An Er Ning granules combined with ceftriaxone sodium in the treatment of children's community-acquired pneumonia, The improvement of TCM syndromes and the safety of clinical application.The design of this study has fully considered the preliminary work basis of Anerning Granules in the treatment of respiratory tract infections, the actual application of pediatric Chinese medicine, and followed the scientific principles of "Pediatrics" and "Pediatrics of Traditional Chinese Medicine" and GCP regulations.

This study will be conducted in 7 hospitals including the First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine. A total of 216 subjects are planned to participate voluntarily.

As the unit responsible for clinical research, the Ethics Committee of the First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine has reviewed the study and believes that the study complies with the Declaration of Helsinki and is in line with medical ethics (ethics approval number: TYLL2018[K] word 018).

2.ho should not participate in this study

(i) chest X-ray film showed obvious lung tumors and tuberculosis;

(ii) people with acute infectious diseases such as measles, whooping cough, or influenza;

(iii) acute upper respiratory tract infection, wheezing bronchitis, bronchial asthma, bronchial foreign bodies or other respiratory diseases;

(iv) children with severe malnutrition and immunodeficiency;

(v) in combination with severe cardiopulmonary disease, liver and kidney disease, advanced tumors, and other serious or progressive diseases;

(vi) those who meet the diagnostic criteria for CAP (severe) Western medicine for children;

(vii) patients with clinical diagnosis or clinical consideration of viral pneumonia and mycoplasma pneumoniae pneumonia;

(viii) people with an allergic constitution or allergy to penicillin, cephalosporin antibiotics, Anerning Granules and their components;

(ix) researchers think it is inappropriate to join the group.

3. What you will need to do if you participate in the study

(1) Screening of subjects

Before enrolling in this study, your child will undergo the following tests to determine whether your child can participate in the study: ①The doctor will ask, record your child's medical history, and perform a physical examination on your child. ②Your child needs to do physical and chemical examinations such as blood routine, chest X-ray, urine routine, electrocardiogram, liver and kidney function, etc.

(2) Research steps

This study used a randomized, double-blind, parallel-armed, multi-center clinical study design method. The subjects were admitted to the hospital for observation and observation. An Erning granules were used for up to 10 days (the clinical recovery can be ended at any time), and they were also treated with basic antibiotics such as ceftriaxone sodium (rochefen). If the body temperature ≥ 38.5 ℃, oral suspension of acetaminophen (Tylenol) can be given orally.

If your child meets the eligibility criteria, and you and your child agree to participate in the study, the doctor will introduce you to the relevant situation of the study, and also ask you to provide your child with the disease-related situation, including the onset process, family History, past history, allergy history, past or present medication status, etc. After medication, the body temperature, cough, expectoration, and sore throat should be recorded every day, and

the TCM syndrome score evaluation should be completed before medication and at the end of the study (10 days of medication); before medication, 5 or 7 days after medication, and at the end of the study Physical examination such as vital signs. In addition, before medication and at the end of the study, you and your child will also need to cooperate with the doctor to complete blood and liver and kidney functions, X-ray chest radiography and other related physical and chemical tests. If your child withdraws from the trial halfway, please also complete the safety check as much as possible, which is also important to ensure the safety of your child.

The above physical and chemical examinations are all routine medical examinations, if your child does not participate in this study, they also need to undergo these examinations.

(3) Usage and dosage of test drugs

Test drugs, including Anerning Granule and Anerning Granule Simulant, were taken orally, 1 to 5 years old, 1 sachet/time, 3 times/day.

In accordance with the conventional treatment protocol for community-acquired pneumonia, all children enrolled in this study were given ceftriaxone sodium (rochefen) as a basic treatment. Ceftriaxone sodium (50mg/kg/time, once/day, the total amount of a day does not exceed 2g). The course of treatment is 10 days. If the clinical recovery is reached during this period, the treatment can be ended.

(4) Other matters that require your cooperation

During the observation period of your child, your child needs to follow the doctor's instructions. The doctor's visit to your child is very important for this study, because the doctor will judge whether the treatment your child receives really works.

If you are not taking the test drug, you must return the unused drug and its packaging, and bring other drugs that you are taking, including drugs that your child has other comorbidities to continue taking.

You need to cooperate with your doctor to record daily temperature, cough, expectoration, and sore throat.

If your child needs other treatment during the study, please contact your child's doctor in advance.

4.Possible benefits of participating in research

Your child and society will likely benefit from this study. Such benefits include:

1. Your condition may be improved;

2. During the study period, you will get free medical services related to this trial;

5.Possible adverse reactions, risks, discomfort and inconvenience in participating in the study

All treatment drugs may have side effects. If your child feels any discomfort during the study, or if there is a new change in the condition, or any unexpected situation, whether it is related to the drug or not, you should notify your child's doctor in time, and the doctor will make a judgment and medical treatment.

The doctor and sponsor Jin Xizang Medicine Co., Ltd. will make every effort to prevent possible adverse drug reactions due to this study. If an adverse reaction occurs in the clinical trial, the doctor will give timely and reasonable diagnosis and treatment, and the supporter will also provide treatment costs and corresponding economic compensation for the adverse reactions related to the trial that require diagnosis and treatment. This has been Provisions are made in the Quality Management Code.

Your child needs to be hospitalized during the study period, and also needs to cooperate with medical staff to complete the corresponding examination, which may cause you trouble or inconvenience.

Any treatment may be ineffective, and the disease may continue to progress due to ineffective treatment or other diseases. This is the treatment risk that every child will be treated. Even if you do not participate in this clinical study, the treatment risk will exist. During the study period, if the doctor finds that the treatment measures taken by this research institute are invalid, the study will be suspended and other treatment measures that may be effective will be replaced.

6. Related expenses

The sponsor, Jinxizang Medicine Co., Ltd., will pay for your child ’ s research-related examinations during the study and provide study drugs free of charge.

If there is damage related to the trial drug, the sponsor will pay the relevant medical expenses. If treatment is required due to serious adverse reactions, the supporter will also provide corresponding financial compensation.

If your child is combined with the treatment and examination required for other diseases at

the same time, it will not be free.

7. Confidentiality of personal information

Your child's medical records (including research medical records and physical and chemical examination reports, CRF) will be kept in the hospital as required. The doctor will record the laboratory test results on your child's outpatient medical record. Food and Drug Administration, ethics committees, researchers and sponsor representatives at all levels will be allowed to consult your child's medical records. Any public report on the results of this research will not disclose your child's personal identity. We will make every effort to protect the privacy of your child's personal medical information within the allowable range.

In addition to this study, it is possible that your child's medical records will be used again in other future studies. You can also now state that you refuse to use your child's medical records in studies other than this one.

8. Access to more information

You can ask any questions about this research at any time. Your child's doctor will leave you the hospital and your phone number so that you can answer your questions.

If you have any complaints about participating in the study, please contact the Ethics Committee Office (telephone number: 022-27986258).

If there is any important new information during the study, which may affect your child's willingness to continue participating in the study, your child's doctor will notify you in time.

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If there is any important new information during the study, which may affect your child's willingness to continue participating in the study, your child's doctor will notify you in time.

10. What to do now

Whether or not to participate in this study is up to you or your child. You can also make a decision after discussing with your family or children.

Before you or your child make a decision to participate in the study, please ask your child's

doctor as much as possible until you fully understand the study.

Thank you for reading the above materials. If your child decides to participate in this study, please tell your child's doctor or research assistant, and they will arrange all matters related to the study for you.

Please keep this information.

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Informed consent form • Signature page

Research project name:Clinical study on evaluation of antibiotic application of Anerning granules based on children's community-acquired pneumonia

Supporting unit: Jinxian Tibetan Medicine Co., Ltd.

National Pharmaceutical Standard: Z20025878

Consent statement:

1. I have read the above introduction about the study and have the opportunity to discuss and ask questions about this study with the doctor. All the questions I raised were answered satisfactorily.

2. I know the benefits and risks of participating in this study. I know that participating in the study is voluntary, and I confirm that I have had enough time to consider it and understand:

(1) I can consult the doctor for more information at any time;

(2) My child can withdraw from this study at any time without discrimination or retaliation, and medical treatment and rights will not be affected;

(3) I also know that if we withdraw from the study halfway, especially when my child withdraws from the study due to drugs, if I tell the doctor about the change in the condition and complete the corresponding physical examination and physical and chemical examination, this will affect the child and the entire Research is very beneficial;

(4) If any other medication is required due to changes in the condition, I will seek the advice of the doctor in advance or tell the doctor truthfully afterwards;

(5) I agree that food and drug supervision and administration departments at all levels, ethics committees, researchers, and sponsor representatives can consult my child's research materials;

(6) I agree that other studies besides this study use my child's medical records:() Agree to hit "√", disagree to hit "×"

In the end, I decided to agree to participate in this study on behalf of my child, and ensured to follow the doctor's advice as much as possible, and promised to keep the original treatment

plan unchanged during the clinical trial observation.

Name of tested child:_____

Signature of the legal representative of the tested child:_____

Relationship with the children tested:_____

Contact number:_____

Date:_____

I confirm that I have explained the details of the trial to the subject’s legal representative (or the child under test), including its rights and possible benefits and risks, and given it a copy of the signed informed consent.

Doctor's signature:_____

Contact number:_____

Date:_____