Informed consent

Part I Instructions for subjects
1. Project introduction
Project name: Evaluation of the efficacy and safety of natural killer (NK) cell injection combined with XELOX chemotherapy to prevent postoperative recurrence and metastasis in patients with colorectal cancer.
This project is a clinical research work.
Study objective:
① This study aims to evaluate the effectiveness and feasibility of combination therapy to solve the problem of postoperative recurrence and metastasis in patients with colorectal cancer.
② This study aims to evaluate the safety of combination therapy to solve the problem of postoperative recurrence and metastasis in patients with colorectal cancer.
③ To further understand whether the effect of chemotherapeutic drugs on NK cells.
Inclusion criteria:
① Informed and consent to join the investigator;
② All included cases (over 18 years old) must be confirmed as stage III CRC by pathology and MSI/dMMR/BARF status by immunohistochemistry. Liver, lung, and peritoneal metastasis will not be considered. Additionally, patients must meet the following criteria: Eastern Cooperative Oncology Group performance status (ECOG PS) ≤ 2. There will be no restrictions based on gender, race, or nationality. In the same original study, the chemotherapy regimen used for the control group of CRC patients is the same as that for the experimental group of CRC patients. The dosage and course of treatment are not limited.
Exclusion criteria
This study excluded patients with interstitial lung disease, autoimmune disease, clinically significant cardiovascular disease, active infection, systemic steroid administration, pregnant women, multiple primary cancers within the previous 5 years, positive human immunodeficiency virus test result, and any other conditions that made the patient unsuitable for this study.

The investigator is the medical staff of general surgery department from the DaZu Hospital of Chongqing Medical University, Chongqing, CHINA; the research unit is the DaZu Hospital of Chongqing Medical University
3. Explain the possible benefits of participation in this study
4. To study the benefits to the subjects themselves: using peripheral blood extraction of natural killer cells combined with XELOX regimen to prevent postoperative recurrence and metastasis in tumor patients.
5. Study possible discomfort and risks to subjects
6. Reduction of capecitabine and oxaliplatin are required for all grade 3 or 4 toxicities due to the study drug. Treatment was continued until disease progression, unacceptable toxicity, or withdrawal of consent.
7. Regarding the cost of participating in the trial None
8. The records of the subject will be kept confidential, but the subject data may be monitored by the relevant departments (Ethics Committee, Food and Drug Administration), but the identity of the subject will not be disclosed.

9. The investigator will answer all the questions about the trial and be able to contact the subject in an emergency. Contact name: Yu Shaohong Contact Number: +86 15877990155

10. Participation in the trial is voluntary and there is no loss of equity or any penalty even if they from the trial.

11. The subject will be explained by the investigator or the designated investigator to fully understand the above, give them full time to consider and make a decision whether to participate in the study.

12. If an unexpected clinical impact is found, it is necessary to modify the informed consent form and confirm it by the subject or his legal representative.

13. If the subject is damaged by the intervention, the investigator or the sponsor should give the subject corresponding compensation or compensation, such as transportation, missed work, insurance and compensation risks.

14. The trial protocol was approved by the ethics committee, and any violation of the study protocol during the trial could complain directly to the hospital ethics committee. Contact number is +8623-43785885.

Part II informed consent signature

1. I have read in detail the natural killer (NK) cell injection combined XELOX chemotherapy prevention of colorectal cancer patients with postoperative recurrence and metastasis effectiveness and safety evaluation of informed consent, my doctor/nurse has made a detailed study plan to me, I fully understand the purpose, nature, method and my rights and risks, learned that my personal data is confidential, privacy is protected.

2. I volunteered to participate in this study and agree to complete this study in accordance with the contents of the study method and the informed consent form. This informed consent is 3 pages, I will get a copy of the signed informed consent.

    Signature

    Date:

Signature of the subject's legal representative (if necessary) Date

I have fully explained and explained to the subject the purpose, the operation process and the possible risks and potential benefits of the subject to participate in the trial, and answered all the relevant questions of the subject satisfactorily.

Principal Investigator or Investigator designated by the Investigator

    Signature

    Date