Application of Tranilast as a Radiosensitizer in the Treatment of Radiotherapy Resistant Nasopharyngeal Carcinoma: a Phase II Clinical Study

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

NCT ID: Not yet assigned

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STUDY PROTOCOL

This study is a prospective intervention phase II trial initiated by researchers to compare the objective remission rate of patients with recurrent nasopharyngeal carcinoma treated with previous radiotherapy, and explore the safety and effectiveness of additional use of Tranilast.

18 patients are to be recruited for this project. It includes the screening period (14 days from the signing of the informed consent to the first oral administration of Tranilast or radiotherapy), the treatment period (the first oral administration of Tranilast or radiotherapy, the time of intolerance or withdrawal from the trial for various reasons) and the follow-up period (12weeks after the last radiotherapy, in which serious adverse events will be 90 days or more after the end of treatment).

After the subjects signed the informed consent, within 3 days before and after the start of radiotherapy, they orally took Tranilast 100mg 3 times a day.Evaluation during treatment: the adverse events were strictly monitored and the severity was graded according to the adverse event standard CTCAE version 5.0. For patients with recurrent nasopharyngeal carcinoma treated by radiotherapy, tranister was treated simultaneously with radiotherapy.

In case of the following circumstances, it can be considered to stop medication: (1) unacceptable adverse events; (2) Concurrent diseases that prevent further treatment; (3) The researcher decided to withdraw from the subject; (5) Subjects withdraw consent; (6) Does not meet the requirements of the trial treatment or procedure; (7) Other reasons.,

After treatment, each subject will be followed up. Subjects should be monitored for adverse events for at least 30 days, and serious adverse events will be collected 12weeks or more after the end of treatment. The subjects will be followed up after treatment for 3 years or until one of the following events: (1) death; (2) start non research cancer treatment; (3) withdraw the research consent; (4) loss follow-up.

The main purpose of this test includes determining orr according to recist1.1, and evaluating safety through various adverse event parameters, including the incidence of adverse events and the time to reach level 3 ~ 5 adverse events for the first time.

Inclusion Criteria:

1. Sign informed consent
2. At least 18 years old on the date of signing the informed consent

3. Previously received standard radical radiotherapy and chemotherapy
4. Recurrent nasopharyngeal carcinoma in situ or cervical lymph nodes confirmed by pathological biopsy and imaging examination
5. After multidisciplinary consultation, there was a clear indication for surgery, and the patient was informed and refused to accept surgical treatment 6）ECOG PS：0/1
6. 7) Laboratory examination confirmed good organ function, which should be carried out within 10 days before the first treatment.

Exclusion Criteria:

1. After evaluation, it does not meet the indications of re-radiotherapy
2. unable to take oral medication
3. Pregnancy or lactation
4. Known allergy to Tranilast
5. Patients who are judged by the researcher as unsuitable to participate in this trial

Data Evaluation and Statistical Methods

The study data were analyzed through IBM SPSS V23 software. In the categorical comparison of the groups, Yates Correction, Fisher's Exact test, and Pearson χ^2 test were employed.

The risk factors were analyzed with Cox regression analysis. In the comparison of survival duration according to VOD status, Log Rank test was employed. The analysis results were presented as mean±standard deviation for the quantitative data and as frequency (percentage) for the categorical variables. Significance level was taken as $p<.05$.

ETHICS

Ethics In conducting study, universal ethical rules as well as scientific principles were observed. As the use of human beings in the study required the protection of individual rights, the principles of Helsinki Declaration of Human Rights were also observed. Ethics board approval was obtained from the Nanfang Hospital of Southern Medical University Ethics Committee (Decision No: NFEC-2022-270) and institutional permission was taken from the hospital where the study would be conducted.