Official Title

Study of Tretinoin Capsules in Combination With Azacitidine and Venetoclax in Treatment Naïve Participants With Acute Myeloid Leukemia

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I.Research protocol

The experimental group will receive a combination therapy of all-trans retinoic acid (ATRA), azacitidine, and venetoclax, while the control group will receive a combination therapy of daunorubicin and cytarabine. All patients need to complete two cycle of induction therapy. After two cycle of induction therapy the patients who are willing to receive bone marrow transplantation can be treated with a bone marrow transplant, and the patients who refuse the bone marrow transplantation can treated with consolidation therapy followed by connective maintenance therapy.

(1) Experimental group:Inductive therapy: AZA 75mg/m² per day for days 1-7 and venetoclax 100mg orally for day 1 , 200mg orally for day 2, 300mg orally for day3-5, 400mg orally for day 6-9,ATRA 45mg/m² for day 11-28,every 28 days for up to 2 cycles or progression; Consolidate therapy:AZA 75mg/m² per day for days 1-7 and venetoclax 100mg orally for day 1 , 200mg orally for day 2, 300mg orally for day3-5, 400mg orally for day6-9,ATRA 45mg/m² for day 11-28,every 28 days for up to 2 cycles or progression; Maintenance therapy:ATRA 45mg/m^2 for d1-21 every 28 days,AZA 70mg/m² per day for days 1-7.Once per month for 4 doses, followed by once every 3 months, commencing concurrently with azacitidine untill progression;

(2) Control group:Inductive therapy: Daunorubicin: 60 mg/m^2 for day 1-3, Cytarabine: 100 mg/m^2 for day 1-7,every 28 days for up to 2 cycles or progression; Consolidate therapy:A chemotherapy regimen with intermediate-dose cytarabine alone or in combination with anthracycline drugs (cytarabine 1.5-2g/m^2),every 28 days for up to 2 cycles or progression; Maintenance therapy:AZA 70mg/m² per day for days 1-7.Once per month for 4 doses, followed by once every 3 months, commencing concurrently with azacitidine untill progression;

II. Study procedure and time frame

The efficacy was assessed within 2 years after treatment, and the assessment indexes included composite complete response (CRc), the overall response rate (ORR), MRD, rate of transfusion independence and overall survival (OS).

III. Conventional treatment plan outside the study

Participants may utilize other "3+7" regimens combining mitoxantrone/idarubicin with cytarabine, or the FLAG-IDA protocol, in addition to this study. Symptoms may be alleviated and the disease may respond to treatment. However, this is often accompanied by side effects such as nausea, vomiting, hair loss, and oral mucositis, which suppress bone marrow function leading to a decrease in white blood cells, red blood cells, and platelets, increasing the risks of infection, anemia, and bleeding. There is also potential for damage to organs such as the liver, kidneys, and heart. Additionally, there may be the development of resistance to certain chemotherapy drugs,

leading to a decrease in therapeutic efficacy or disease non-response. It is not guaranteed to be more effective than existing treatments.

IV. Clinical data processing and confidentiality of clinical research data

The information and data recorded by the subjects participating in the study will be kept strictly confidential and will not be disclosed, and if the study results are published, the subjects identity information will also be kept confidential. At the same time, conduct regular patient follow - up, data detection, and complete data entry. After all the data have been collected, use SPSS 23.0 statistical software for data processing and analysis.