Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation and comparison of the effectiveness of Hyper CVAD and Arsenic/ interferon/ zidovudine (As/IFN/AZT) treatment regimens in patients with acute Adult T-cell leukemia (ATL).

Protocol summary

Study aim

This study aimed to evaluate and compare the effectiveness of Hyper-CVAD and Arsenic/ interferon/ zidovudine (As / IFN / AZT) regimens In the treatment of acute adult T-cell leukemia (ATL).

Design

The controlled clinical trial with parallel groups was carried out as a double-blind, randomized study, phase 2 of which was conducted on 36 patients. The randomization based on sealed envelopes was performed using the Randomaize.com website.

Settings and conduct

ATL patients referred to Mashhad University of Medical Sciences will be randomly divided into intervention and control groups and The As / IFN / AZT and Hyper CVAD drug regimens would be prescribed for 60 days, and in case of drug poisoning, not only the doses would be reduced but also the time period would be reduced by half if the individuals were intolerant. Prior to the research, all participants would undergo routine tests including CBC, biochemistry, viral serology, and chest, abdomen, and pelvic CTs. A stool test would also be performed to check for strongyloidesstercoralis infection. CBC and biochemical tests would be repeated once a week. In this study, participants are blinded to the intervention received based on codes (codes A and B).

Participants/Inclusion and exclusion criteria

The inclusion criteria were acute ATL, over18 years of age, a positive human T-cell lymphotropic virus type 1 (HTLV-I) serological test performed with enzyme-linked immunosorbent assay (ELISA) or Polymerase chain reaction (PCR). The exclusion criteria were the existence of underlying diseases, the use of drugs that interfered with the treatment regimens.

Intervention groups

The Hyper CVAD drug regimen was prescribed to the intervention group. The control group would receive the As / IFN / AZT regimen.

Main outcome variables

Complete remission, the overall survival rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210703051770N1**
Registration date: **2022-04-29, 1401/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-29, 1401/02/09**
Update count: **0**

Registration date

2022-04-29, 1401/02/09

Registrant information

Name

Mostafa Kamandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 647 3293

Email address

kazem3293@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-25, 1401/01/05

Expected recruitment end date

2022-05-26, 1401/03/05

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation and comparison of the effectiveness of Hyper CVAD and Arsenic/ interferon/ zidovudine (As/IFN/AZT) treatment regimens in patients with acute Adult T-cell leukemia (ATL).

Public title
Evaluation and comparison of treatment regimens in patients with acute leukemia.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having acute ATL Being over 18 years of age Having a positive HTLV-I serological test result performed with ELISA
Exclusion criteria:
Taking drugs that interfere with the treatment regimens used Withdrawing from the study
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization: This type of randomization will be done using the site https://www.sealedenvelope.com. In this method, the volume of each block must first be determined. Then, a list of the blocks are prepared and numbers are assigned to each (AABB (1) - ABAB (2) - ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)). In the next step, random numbers from 1 to 6 are selected (e.g. 1 4 5, etc.) and finally, the treatment allocation list is specified based on the previous random numbers (AABB-BBAA-BABA-...).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants are blinded to the intervention received based on codes (codes A and B) that people are unaware of the type of intervention received and only researchers are aware of it. Also, the drugs are the same in shape, color and coating to allow blindness at the participant level.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Department of Internal medicine, Emam Reza Hospital, Mashhad.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Approval date
2021-11-30, 1400/09/09
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.717

Health conditions studied

1

Description of health condition studied
Acute T cell leukemia
ICD-10 code
C91.5
ICD-10 code description
Adult T-cell lymphoma/leukemia (HTLV-1-associated)

Primary outcomes

1

Description
Complete Remission
Timepoint
Weekly from before the intervention (beginning of the study) to 60 days after the intervention
Method of measurement
Based on complete response to treatment (Achieving remission or not getting remission) Through chemical tests and CBC

2

Description
One-year survival
Timepoint
On a daily basis from before the intervention (beginning of the study) to 60 days after the intervention
Method of measurement
Based on the individuals' survival rate (Calculate the

number of days to survive until death) Through the occurrence of death in two groups

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, the Hyper CVAD drug regimen is performed in alternating cycles A and B. Cycle A: Cyclophosphamide 300 mg / m2 every 12 hours on days 1, 2, and 3. Vincristine 2 mg / m2 on days 4 and 11. Adriamycin (doxorubicin) 50 mg / m2 on day 4 Dexamethasone 40 mg on days 1, 4, 11, 12, 13 and 14. Methotrexate 12.5 mg with dexamethasone 4 mg intrathecally on day 2. Cycle B: Methotrexate 1 g / m2 on day 1. Cytosar 3 g / m2 every 12 hours on days 2 and 3. Intrathecal methotrexate on day 2. Cyclophosphamide (importer of Sina Pishgam Drug New), Wayne Christine (importer of Valian Drug), Adriamycin (Behestan Drug Company), Vial of methotrexate (Kavosh Daro Gostar Co.), Interferon (Aktor and Sinagen Co.)

Category

Treatment - Drugs

2

Description

Control group: Intravenous arsenic 10 mg daily for 5 days a week. Subcutaneous interferon 5 million units per day. Zidovudine 900 mg daily in 3 doses.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Mostafa Kamandi

Street address

Department of Internal medicine, Emam Reza Hospital, Mashhad.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 915 113 5741

Email

kamandim@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mostafa Kamandi

Street address

Department of Internal medicine, Emam Reza Hospital, Mashhad.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 915 113 5741

Email

kamandim@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mostafa Kamandi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Department of Internal medicine,Emam Reza Hospital, Mashhad.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316
Phone
+98 915 113 5741
Fax
Email
kamandim@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mostafa Kamandi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Department of Internal medicine,Emam Reza Hospital, Mashhad.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 915 113 5741
Fax
Email
kamandim@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mostafa Kamandi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Department of Internal medicine,Emam Reza Hospital, Mashhad.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 915 113 5741
Fax
Email
kamandim@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Because the researchers follow ethical standards, the information of all the participants will be recorded anonymously, and their informed consent on the publication of the research results will be got to avoid any problems regarding the publication of the study data.
When the data will become available and for how long
Eight to twelve months after the publication of the study results.
To whom data/document is available
The researchers working in scientific centers and academic institutions.
Under which criteria data/document could be used
1- Contributing to continue clinical research in this field 2- Using in systematic reviews 3- Performing more statistical analyzes to improve the reporting accuracy and reduce possible errors.
From where data/document is obtainable
Sending a written request to the project manager and all the researchers involved in the project. Mostafa Kamandi: kamandim@mums.ac.ir
What processes are involved for a request to access data/document
Corresponding with the clinical trial director; 2- Consultation of the clinical trial director with other researchers involved in the project; 3- Obtaining permission from other members; 4- Corresponding with the faculty to provide the data; 5- In case of a positive answer, corresponding and sending the data in accordance with the request.
Comments