# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Aug 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.

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**Email**
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**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

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## Person responsible for updating data

**Contact**

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Mashhad University of Medical Sciences

**Full name of responsible person**

Mostafa Kamandi

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## 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**