











ANKARA ONCOLOGY TRAINING AND RESEARCH HOSPITAL CLINICAL RESEARCH CENTER & PHASE I CLINICAL RESEARCH CENTER







ANKARA ONCOLOGY HOSPITAL TRAINING AND RESEARCH HOSPITAL



- Ankara Oncology Hospital is an academic comprehensive cancer center in Turkey.
- We take care of over 1 million patients per year.
- There are 10,000 new cancer diagnoses.
- There is a university hospital that provides education in 24 departments or divisions and serves a total of 42 specialties.
- It has the largest medical oncology and hematology clinics in Turkey.
- It has a center that performs all types of stem cell transplants, including over 100 autologous, allogeneic, cord blood, and haploidentical transplants per year, and we have performed over 2,000 stem cell transplants to date.









Prof. Dr. Fevzi ALTUNTAŞ Director, Clinical Research Center





Fevzi Altuntas

Professor of Medicine, Ankara Yildinim Beyazit University ybu.edu.tr üzerinde doğrulanmış e-posta adresine sahip - Ana Sayfa

ALINTI YAPANLAR

Hematology Bone Marrow Transplantation Leukemia Lymphoma Myeloma

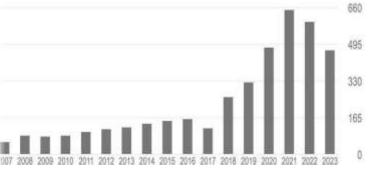
 Hepsi
 2018 yılından bugüne

 Citations
 4202

 H index
 29

 110 index
 65

KATKIDA BULUNAN YAZARLAR



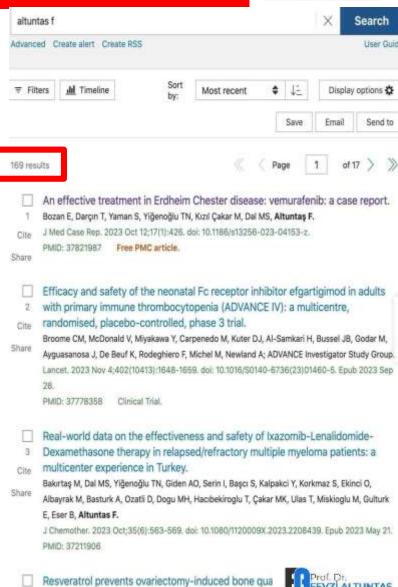
• Article:

- Around 200 SCI/E
- Over 60 nationally indexed journals
- Citation: Over 4500
- Poster: Around 800
- Book/Book chapter: Around 70
- H index: 30
- I10 index: 67











CLINICAL RESEARCH CENTER



JACIE 3





JACIE inspector certifications

this is to certify that

Fevzi Altuntas

has passed the 8th Edition JACIE Inspector Exam:

Inspection Process, Techniques and Common Standards

Friday, 20 January 2023

Kim Orchard
Chair, JACIE Committee





Online Education

this is to certify that

Fevzi Altuntas

has passed the 8th Edition JACIE Inspector Exam:

Clinical Standards

Friday, 20 January 2023

Fire Children







CLINICAL RESEARCH CENTER



EBMT cellular therapy certifications



this is to certify that:

Tugce Nur Yigenoglu

Has a chieved the accreditation of the knowledge of the main topics from the curriculum of the European Society for Blood and Marrow Transplantation

with 88%

The accreditation will last five years

47th Annual Meeting [Virtual Edition] - 14th March 2021

Nicolaus Kröger EBMT PRESIDENT



This is to certify that:

Bahar Uncu Ulu

Has achieved the accreditation of the knowledge of the main topics from the curriculum of the EBMT

with 84%

The accreditation will last five years

48th Annual Meeting of the EBMT - 20 March 2022

From

Anna Sirrada
EBMT PRESIDENT













FAALIYET IZIN BELGESI IZIN NUMARASI E1M/2023/06 Sağlık Bilimleri Üniversitesi MERKEZÎN ADI Ankara Abdurrahman Yurtaslan Onkoloji Eğitim ve Arastırma Hastanesi Faz 1 Merkezi Dr. Abdurrahman Yurtaslan Ankara Onkoloji Eğitim ye Araştırma Hastanesi MERKEZIN ADRESI Mehmet Akif Ersoy Mah. Vatan Cad. No. 91 06200 Yenimahalle /Ankara llaç ve Biyolojik Ürünlerin Klinik Azaştırmaları YASAL DAYANAK Hakkında Yönetmelik Faz I Klinik Araştırmalar ☐ Biyoyararlanım/Biyoeşdeğerlik Çalışmaları IZNÍN KAPSAMI □ Klinik ☐ Biyoanalitik Dr. Asım HOCAOĞLU ONAVLAVAN YETKİLİ **IMZA** TARIH 24/02/2023 EK · Yetkili Personel Listesi * Yukarıda bileileri verilen merkezin İlac ve Bizaloilk Ürünlerin Klinik Arasternaları Hakkında Yönetmelik ve ulusal/uluslararası mevzuat gerekliliklerini karşıladığı ve faaliyet kapsamında belirtilen klinik araştırmaların yürütülmesi yönünden uygun olduğu Türkiye İlaç ve Tibbi Ciha;

geçerliliği risk bazlı olarak periyodik değerlendirmeye tabidir.

SAĞLIK BAKANLIĞI

Türkiye İlaç ve Tibbi Cihaz Kurumu



January 16, 2019 T.C. February 24, 2023 SAGEJK BAKANLIGE Tarking Buy or Tobbs Clinic Korneys January 12,2024 FAALÍVET IZÍN BELGESÍ

2019-2024

Completed Phase 1 Study:13

- Hematology
- Oncology
- Infectious Diseases

Running Phase 1 Study:9

- Hematology
- Oncology
- Infectious Diseases



TAXABLE PROPERTY.

EZÉN NUNEARANI

SHERRICZEN ADE

MEDICATED ADDRESS

VANAL DAYANAR

IZNIN KAPSAMI

DMCA

TABLE

ONAYLAYAN YETKILI

FIMINIARI

Saglish Billiandoot Christopatoni

ve Academia Barlanon

Hakkesda Vönetnedik

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12/01/2024 Yelish Persond Liston

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Ankara Abdurrahman Yuntadan Onkologi Eğirim ve

Dr. Abdansbrown Yunterlan Aukaro-Christini Egirim

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Boyen Telelo Distalorio Klinik Aragortushen

☐ Biomandanes Biomandanià Calonala



ANKARA ONCOLOGY HOSPITAL PHASE I CLINICAL RESEARCH AND CLINICAL RESEARCH CENTER



Dr. Abdurrahman Yurtaslan Ankara Oncology Training and Research Hospital Clinical Research Center and Phase I Oncology Research Center provide services in accordance with international standards and local legislation.

The Clinical Research Center has been licensed by the Turkish Medicines and Medical Devices Agency since 2017, and the Phase I Pharmaceutical Research Center has started to provide services since 2019.





PHASE I CLINICAL RESEARCH AND CLINICAL RESEARCH CENTER



Clinical studies carried out at Abdurrahman Yurtaslan Ankara Oncology Training and Research Hospital Clinical Research Center and Phase I Research Center provide services with an experienced team in their field and fully equipped work areas, and the Phase I, Phase II, It is one of the leading clinical research centers in our country with Phase III and Phase IV clinical studies.











4-Bed Clinical Unit















Physician's Room

for all patient areas

Nurse's Room

Archive (Restricted access)

Volunteer lounge area

Investigational Product Storage Room (Restricted access)

Laboratory

-Refrigerated and Room temperature Centrifuge -80° C Freezer -Biological safety







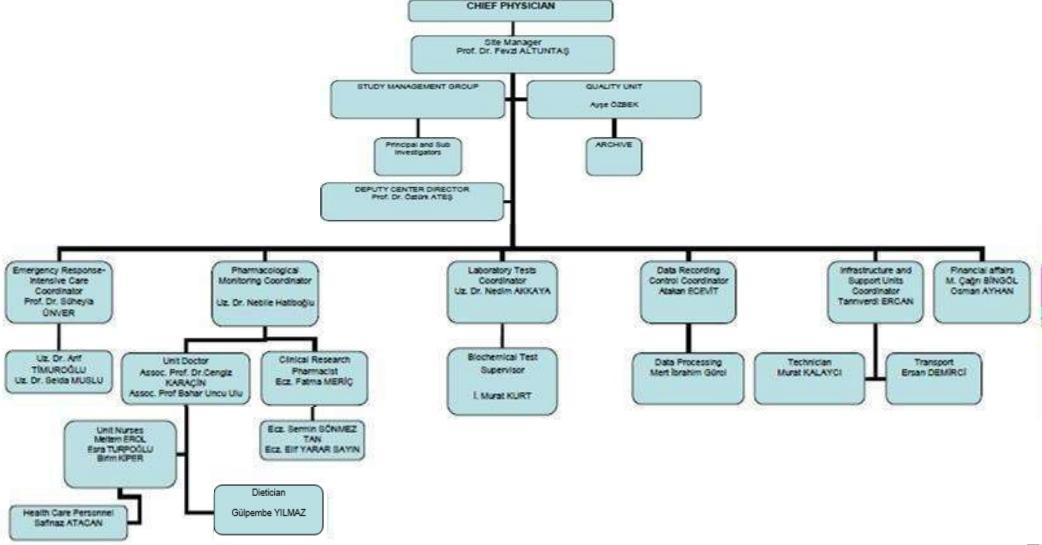






PHASE I CLINICAL RESEARCH CENTER STAFF DELEGATION SCHEMA









ANKARA ONCOLOGY HOSPITAL

PHASE I CLINICAL RESEARCH AND CLINICAL RESEARCH CENTER



MEDICAL ONCOLOGY

INVESTIGATORS

HEMATOLOGY

Prof. MD: 5

Assoc. Prof. MD: 4

Specialist MD: 5

PI and Sub-I= 14



Clinical Pharmacology

Prof. MD: 1

Specialist MD: 1



Assoc. Prof. MD: 3

Specialist MD: 6

PI and Sub-I= 12





STUDY TEAM CERTIFICATES



The team involved in Clinical Research;

- Good Clinical Practices (GCP)
- ICH-GCP (International Conference on Harmonization-Good Clinical Practice)
- IATA (Integrated Approaches to Testing and Assessment)
- EBMT certification for cellular therapy
- Site Specific Trainings







NEW DIAGNOSI REFRACT	· ·	DIAGNOSIS	PATIENT RECRUITMENT STATUS
Newly diag	nosis	Autoimmune Cytopenia	RECRUITING
Advanced 9		Non- Small Cell Lung Cancer	RECRUITING
Advanced S	Stage	Non- Small Cell Lung Cancer	RECRUITING
Low-Intermed	liate Risk	Crimean-Congo Hemorrhagic Fever Disease	RECRUITING
Local/Adva /Metasta		Solid Tumor	RECRUITING







NEW DIAGNOSIS\RELAPSE REFRACTORY	DIAGNOSIS	PATIENT RECRUITMENT STATUS
Advanced Stage /Metastatic	Non- Small Cell Lung Cancer	RECRUITING
Advanced Stage /Metastatic	Solid Tumor	RECRUITING
Relapsed/Refractory	Diffuse Large B Cell Lymphoma	RECRUITING
Stage II-IIIA	Non-small Cell Lung Cancer	RECRUITING
Metastatic	Breast Cancer	NOT YET RECRUITING







NEW DIAGNOSIS\RELAPSE REFRACTORY	DIAGNOSIS	PATIENT RECRUITMENT STATUS
Relapse Refractory + Newly Diagnosed	Myelofibrosis	CLOSED
Relapse Refractory	Acute Myeloid Leukemia	CLOSED
Relapse Refractory	Multiple Myeloma	CLOSED
Advanced Stage /Metastatic	Non- Small Cell Lung Cancer	CLOSED
Relapse Refractory	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma /Mantle Cell lymphoma	CLOSED
Relapse Refractory	Acute Myeloid Leukemia	CLOSED







NEW DIAGNOSIS\RELAPSE REFRACTORY	DIAGNOSIS	PATIENT RECRUITMENT STATUS
Advanced Stage	Solid Tumor	CLOSED
Newly diagnosis	Covid-19	CLOSED
HER2 (-)	Gastric Adenocarcinoma	CLOSED
Advanced Stage /Metastatic	Solid Tumor	CLOSED
-	Non-transfusion dependent Betathalassemia /Low Risk Myelodysplastic Syndrome	CLOSED
Advanced Stage	Solid Tumor	CLOSED





PHASE I CLINICAL RESEARCH & CLINICAL RESEARCH CENTER Hematology



47 clinical studies have been conducted in the field of Hematology from 2017 to 2023. The numerical ratio of these studies according to phase studies is:

Phase I Studies: 6

Phase II Studies: 11

Phase III Studies: 29

Phase IV Studies: 1





PHASE I RESEARCH & CLINICAL RESEARCH CENTER Hematology



There are 32 clinical studies actively ongoing in 2024





The Phase I Drug Research Center has first conducted studies on beta thalassemia or myelodysplastic syndrome disease since 2020. Studies have also been conducted on diseases such as Covid-19, B Cell Malignancies, Myelofibrosis, Acute Myeloid Leukemia, and Multiple Myeloma.





PHASE I CLINICAL RESEARCH & CLINICAL RESEARCH CENTER Medical Oncology



54 studies have been conducted in the field of Medical Oncology from 2017 to 2023. The numerical ratio of these studies according to phase studies is:
Phase I Studies: 5
Phase II Studies: 10
Phase III Studies: 38
Phase IV Studies: 1



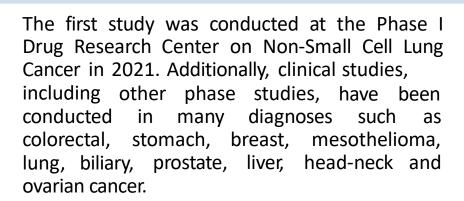


PHASE I CLINICAL RESEARCH & CLINICAL RESEARCH CENTER Medical Oncology



There are 35 clinical studies actively ongoing in 2024









ANKARA ONCOLOGY HOSPITAL CLINICAL RESEARCH CENTER



YEAR	NUMBER OF PATIENTS INCLUDED IN CLINICAL STUDIES
2022	154
2023	162

• It is waiting to open approved 34 Phase 1-3 studies by the end of 2024.





"CAR" T Cell Trials



- Three different clinical studies (Phase I- I/II)
- Autologous (Phase I/II)
 - mRNA is used to transfer genetic material
 - BCMA-targeted second generation CAR T cell
 - Newly diagnosed MM with high risk genetic features
- Allogeneic CAR-T (Phase I/II)
 - BCMA targeted
 - Fifth generation CAR T cell
 - Refractory MM that has received at least three lines of therapy







"CAR" T Cell Trials



CAR-T treatment side effect experience

- 39 total infusions
- Autologous CAR-T (n1=3, n2=4)
 - Grade 1 CRS (fever, fatigue, muscle and joint pain, headache) was observed and responded to paracetamol
 - Grade 1 Neurotoxicity (tendency to sleep) was observed, spontaneous regression was observed.
- Allogeneic CAR-T (n=3)
 - Grade 2 anemia, grade 2 leukopenia, grade 2 neutropenia and grade 1 thrombocytopenia were observed.
 - No Grade 3-4 adverse events were observed.





REGISTRY for HEMATOLOGY RESEARCH



CANCER TYPE	2024
Diffuse Large B-cell Lymphoma	577
Follicular Lymphoma	121
Chronic Lymphocytic Leukemia	312
Chronic Myelogenous Leukemia	166
Mantle Cell Lymphoma	56
Marginal Zone Lymphoma	120
Myelodysplastic Syndrome	121
Multiple Myeloma	399
Peripheral T Cell Lymphoma	64
Immune Thrombocytopenia	126
Hodgkin Lymphoma	535
Acute Myelogenous Leukemia	262
Acute Lymphoblastic Leukemia	136
Chronic Myeloproliferative Neoplasms	338

Total Number of Patients Registered in the Database for Related Diseases: 3610





REGISTRY for HEMATOLOGY RESEARCH



Number of patients in oncology hospital registry in 2017-2023



• Lymphoma: 8249

Myeloma: 5910

• Leukemia: 4962

• HCT: 1890

• Others: 2099





REGISTRY for MEDICAL ONCOLOGY RESEARCH



Cancer Type	2024
Lung	1153
Brain	118
Renal	112
Melanoma	161
Liver	45
Colorectal	1007
Breast	3124
Bladder	129
Stomach	518
Ovarian	396
Pancreatic	119
Cancer Of Unknown Primary	184
Prostate	411
Sarcoma	171
Testicular	74

Total Number of Patients Registered in the Database for Related Diseases: 9154





ETHICS COMMITTEE



- University of Health Sciences, Dr. Abdurahman Yurtarslan Ankara Oncology Training and Research Hospital, Clinical Research Ethics Committee which was established with the approval of Turkish Medicines and Medical Devices Agency (TITCK) in accordance with the principles of the Regulation on Clinical Research of Drugs and Biological Products.
- The aim of the Clinical Research Ethics Committee is to protect the rights, safety and well-being of volunteers taking part in clinical research, taking into account the scientific method and the concerns of the society.
- By acting in accordance with the current Declaration of Helsinki and following national and international standards on Good Clinical Practice, the Ethics Committee ensures timely, comprehensive and independent review of the ethical aspects of the submitted studies.





ETHICS COMMITTEE



- The Member List of the Clinical Research Ethics Committee has 13 members, consisting of people working in the scientific branches listed below.
 - Microbiology
 - Medical Oncology
 - Urology
 - Pharmacology
 - Radiology
 - Hematology

- Patology
- Radiation oncology
- General Surgery
- Anesthesia
- Lawyer
- Teacher





ETHICS COMMITTEE



- Clinical Research Ethics Committee sessions take place every 2 weeks.
- The decision process with the application to the Ethics Committee takes 2 weeks.
- It meets every week when necessary.







PROCESS OF THE CONTRACT & BUDGET



- Clinical research contract and budget negotiations can begin simultaneously with ethics committee applications.
- The approval process of the contract and budget takes an average of 1-2 weeks.







SITE COORDINATORS



The Clinical Research Center Field Coordinator is primarily given the following training:

- Center and Hospital Orientation Training
- Personal Data Protection (KVK) Training
- Basic Level Oncology Training
- Basic Level Clinical Research Training
- Advanced Level Clinical Research Training
- Study Design and Study-specific protocol training
- Electronic System Information Training
- Data Entry Systems Training
- Quality Management System Training
- Clinical research Journal "Club" hours







CLINICAL RESEARCH CENTER SCIENTIFIC MEETINGS









many people (12)





Uyarlanabilir ve Yenilikçi Araştırma Tasarımları
V. KLİNİK ARAŞTIRMALAR
SEMPOZYUMU



KLİNİK ARAŞTIRMALAR MERKEZİ AÇILIŞ TÖRENİ VE SEMPOZYUMU



IV.Klinik Araştırmalar Sempozyumu Tür Tü Meeting üygülarıcı ile ordine taplant alacaktır. https://giobat.gotomeeting.com/join/480284733









CLINICAL RESEARCH CENTER SCIENTIFIC MEETINGS













