



# Randomized, Open-Label, Phase II, Multicenter, Multi-Country Study to Evaluate Safety and Efficacy of Dasatinib 50 mg in First-Line Treatment of Early Chronic Phase Chronic Myeloid Leukemia

22/11/2024 11:40:09

## Main Information

**Primary registry identifying number**

LBCTR2019010169

**Protocol number**

LPI-JOR-LEB-KSA-TUN-2017-01

**MOH registration number**

**Study registered at the country of origin**

Yes

**Study registered at the country of origin: Specify**

**Type of registration**

Prospective

**Type of registration: Justify**

N/A

**Date of registration in national regulatory agency**

05/11/2018

**Primary sponsor**

Hikma Pharmaceuticals

**Primary sponsor: Country of origin**

Jordan

**Date of registration in primary registry**

30/03/2020

**Date of registration in national regulatory agency**

05/11/2018

**Public title**

Randomized, Open-Label, Phase II, Multicenter, Multi-Country Study to Evaluate Safety and Efficacy of Dasatinib 50 mg in First-Line Treatment of Early Chronic Phase Chronic Myeloid Leukemia

**Acronym**

NA

**Scientific title**

Randomized, Open-Label, Phase II, Multicenter, Multi-Country Study to Evaluate Safety and Efficacy of Dasatinib 50 mg in First-Line Treatment of Early Chronic Phase Chronic Myeloid Leukemia

**Acronym**

NA

**Brief summary of the study: English**

The primary endpoint to be measured during the study is the proportion of patients who achieve and maintain MMR at 12 months using RQ-PCR test. The study will be a multicenter, prospective, open-label, randomized Phase II study with a parallel design. Eligible patients with Ph+ CP CML will be randomly assigned to receive either dasatinib 50 mg QD or dasatinib 100 mg QD. The duration of patient participation will be 18 months.

**Brief summary of the study: Arabic**





الهدف الأساسي من الدراسة هو قياس نسبة المرضى الذين يحققون استجابة جزئية كبرى (MMR) شهراً باستخدام اختبار تفاعل سلسلة البوليميراز الكمي اللحظي 12 ويحافظون عليها خلال (RQ-PCR) في المرضى المؤهلين الذين يعانون من سرطان الدم النقوي المزمن الذي يحتوي على الكروموسوم فيلادلفيا. إيجابي في المرحلة المزمنة وتم توزيعهم بشكل عشوائي في ملغم مرة واحدة يومياً) أو جرعة 50 ملغم (يتم تناولها في هيئة قرص واحد 50 مجموعات العلاج لتلقي جرعة يومية من دواء دازاتينيب تبلغ يومية . ملغم مرة واحدة يومياً 50 ملغم (يتم تناولها في هيئة قرصين بحجم 100 من دواء دازاتينيب تبلغ) دراسة عشوائية، مفتوحة التسمية، من المرحلة الثانية، متعددة المراكز في دول متعددة. شهراً 18 ستكون مدة المشاركة

**Health conditions/problem studied: Specify**

Early Chronic Phase Chronic Myeloid Leukemia

**Interventions: Specify**

dasatinib 50 mg QD or dasatinib 100 mg QD

**Key inclusion and exclusion criteria: Inclusion criteria**

Age  $\geq$  18 years.  
Diagnosis of Ph+ or BCR-ABL positive CML in early CP (i.e. time from diagnosis <12 months).  
Clonal evolution  
ECOG performance of 0-2.  
Adequate end organ function

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender**

**Key inclusion and exclusion criteria: Age minimum**

18

**Key inclusion and exclusion criteria: Age maximum**

100

**Key inclusion and exclusion criteria: Exclusion criteria**

NYHA cardiac class 3-4 heart disease  
Cardiac symptoms  
History of significant bleeding disorder  
Patients with active uncontrolled psychiatric disorders  
Pregnant or breast-feeding women  
Patients in late chronic phase (i.e. time from diagnosis to treatment >12 months), accelerated phase (except as noted in inclusion criteria 2) or blast phase

**Type of study**

Interventional

**Type of intervention**

Pharmaceutical

**Type of intervention: Specify type**

N/A

**Trial scope**

Therapy

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Open (masking not used)

**Study design: Control**

Dose comparison

**Study phase**

1

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Parallel

**Study design: Specify assignment**

N/A

**IMP has market authorization**

**IMP has market authorization: Specify**



No

**Name of IMP**

Dasatinib

**Year of authorization**

**Month of authorization**

**Type of IMP**

Others

**Pharmaceutical class**

Tyrosine Kinase Inhibitor

**Therapeutic indication**

early chronic CML

**Therapeutic benefit**

Reduce the rate of adverse events and decrease cost of medications with the dose 50 mg while maintaining the efficacy.  
enhance treatment compliance

**Study model**

N/A

**Study model: Explain model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**Time perspective: Explain time perspective**

N/A

**Time perspective: Specify perspective**

N/A

**Target follow-up duration**

**Target follow-up duration: Unit**

**Number of groups/cohorts**

**Biospecimen retention**

None retained

**Biospecimen description**

NONE

**Target sample size**

100

**Actual enrollment target size**

100

**Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

07/03/2019

**Date of study closure: Type**

Actual

**Date of study closure: Date**

30/06/2022





<b>Recruitment status</b> Recruiting	<b>Recruitment status: Specify</b>
<b>Date of completion</b> 30/06/2022	
<b>IPD sharing statement plan</b> No	<b>IPD sharing statement description</b> NONE
<b>Additional data URL</b> NA	
<b>Admin comments</b>	
<b>Trial status</b> Approved	

Secondary Identifying Numbers	
Full name of issuing authority	Secondary identifying number
Jordan Food and drug administration JFDA	2/1/8/44334

Sources of Monetary or Material Support	
Name	
Hikma Pharmaceuticals	

Secondary Sponsors	
No Sponsors	



## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Zeina Ayoub	Ramlet El Bayda	Lebanon	76898970	zayoub@hikma.com	Hikma Pharmaceuticals
Scientific	Ruba Jaber	Amman	Jordan	00962797486999	rjaber@hikma.com	Hikma Pharmaceuticals
Public	Ali Bazarbachi	AUBMC	Lebanon	03612434	bazarbac@aub.edu.lb	AUBMC

## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
AUBMC	Ali Bazarbachi	Oncologist	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	07/12/2018	Fuad Ziyadeh	irb@aub.edu.lb	01350000
American University of Beirut Medical Center renewal	29/07/2019	Fuad Ziyadeh	irb@aub.edu.lb	01350000

## Countries of Recruitment

Name
Jordan
Tunisia
Saudi Arabia
Lebanon

## Health Conditions or Problems Studied

Condition	Code	Keyword
Chronic Myeloid leukemia	Leukaemia of unspecified cell type (C95)	C95



## Interventions

Intervention	Description	Keyword
Elpida	Dasatinib as monohydrate	DAS

## Primary Outcomes

Name	Time Points	Measure
major molecular response (MMR)	at 12 months	Real-Time Quantitative Polymerase Chain Reaction (RQ-PCR) test

## Key Secondary Outcomes

Name	Time Points	Measure
safety and tolerability of dasatinib	W2,M1,M2,M3,M6,M9,M12,M18	number, type, severity and frequency of adverse events (AEs), serious AEs (SAEs), and clinically relevant changes in laboratory tests according to laboratory reference ranges.
Transformation free survival (TFS)	Baseline,M3,M6,M9,M12,M18	FISH, PCR
Event free survival (EFS)	Baseline,M3,M6,M9,M12,M18	FISH, PCR
Blastic phase (BP) transformation	Baseline,M3,M6,M9,M12,M18	FISH, PCR
Overall survival (OS)	at study end	% of survived patients
Complete cytogenetic response (CCyR) at 12 months	M12	FISH test
Complete molecular response (CMR) at 18 months	M18	PCR
changes in health-related quality of life (HRQOL)	baseline, M6, M12, M18	EORTC QLQ-CML24 questionnaire
treatment compliance	W2,M1,M2,M3,M6,M9,M12,M18	Checking the medication



## Trial Results

**Summary results**

**Study results globally**

**Date of posting of results summaries**

**Date of first journal publication of results**

**Results URL link**

**Baseline characteristics**

**Participant flow**

**Adverse events**

**Outcome measures**

**URL to protocol files**