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

14/12/2025 07:53:55

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
29/06/2021

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
جزيئية كبرى(MMR)
شهرًا باستخدام اختبار تفاعل سلسلة البوليميراز الكمي اللحظي12ويحافظون 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 يوميًا) أو جرعة50 ملغم (يتم تناولها في هيئة قرص واحد 50مجموعات العلاج لتلقي جرعة يومية من دواء دازاتينيب تبلغ
يومية
ملغم مرَّة واحدة يوميًا50 ملغم (يتم تناولها في هيئة قرصين بحجم 100من دواء دازاتينيب تبلغ) .
دراسة عشوائية، مفتوحة التسمية، من المرحلة الثانية، متعددة المراكز في دول متعددة.
شهرًا18ستكون 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 ≥ 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

Recruitment status
Recruiting

Recruitment status: Specify

Date of completion
30/06/2022

IPD sharing statement plan
No

IPD sharing statement description
NONE

Additional data URL
NA

Admin comments

Trial status
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
American University of Beirut Medical Center protocol amendment	04/06/2021	Deborah Mukherji	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,M 18	FISH, PCR
Event free survival (EFS)	Baseline,M3,M6,M9,M12,M 18	FISH, PCR
Blastic phase (BP) transformation	Baseline,M3,M6,M9,M12,M 18	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