



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

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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 يوميًا) أو جرعة 50 ملغم (يتم تناولها في هيئة قرص واحد 50 مجموعات العلاج لتلقي جرعة يومية من دواء دازاتينيب تبلغ يومية . ملغم مرة واحدة يوميًا 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. شهرًا 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



| | |
|---|--|
| 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 |

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