

#### Rasha 123

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Primary registry identifying number

LBCTR2018090151

MOH registration number

20555/2018

Study registered at the country of origin

Yes

Type of registration

Prospective

Date of registration in national regulatory agency

15/09/2018

**Primary sponsor** 

Rasha

Date of registration in primary registry

02/12/2019

**Public title** 

Rasha 123

Scientific title

Rasha 123

Brief summary of the study: English

**Great Job** 

Brief summary of the study: Arabic

السجل الوطني

Health conditions/problem studied: Specify

Heart Failure

Interventions: Specify

New medication

Key inclusion and exclusion criteria: Inclusion criteria

all adults

Key inclusion and exclusion criteria: Gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Exclusion criteria

**Protocol number** 

Rasha123

Study registered at the country of origin: Specify

Type of registration: Justify

N/A

Primary sponsor: Country of origin

Lebanon

Date of registration in national regulatory agency

15/09/2018

**Acronym** 

RH

Acronym

RH

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age maximum

75



less than 18

Type of study

Interventional

Type of intervention

Pharmaceutical

Trial scope

Therapy

Study design: Allocation

Non-randomized controlled trial

Study design: Control

Uncontrolled

Study design: Purpose

Treatment

Study design: Assignment

Other

IMP has market authorization

No

Name of IMP

In Love

Type of IMP

Others

Pharmaceutical class

heart diseases

Therapeutic indication

to treat heart failure

Therapeutic benefit

increase ejection fraction

Study model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Specify perspective

N/A

Type of intervention: Specify type

pharmaceutical with behavioral

Trial scope: Specify scope

N/A

Study design: Masking

N/A

Study phase

1 to 2

Study design: Specify purpose

Study design: Specify assignment

single arm

IMP has market authorization: Specify

USA

Year of authorization Month of authorization

2014

Study model: Explain model

N/A

Time perspective: Explain time perspective

N/A



Target follow-up duration Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retentionBiospecimen descriptionSamples without DNADNA saliva samples

Target sample size Actual enrollment target size

1000

Date of first enrollment: Type Date of first enrollment: Date

Anticipated 20/10/2018

Date of study closure: Type Date of study closure: Date

Anticipated 20/10/2020

Recruitment status Recruitment status: Specify

Date of completion

Not recruiting

IPD sharing statement plan IPD sharing statement description

No I do not want to share

Additional data URL

later

**Admin comments** 

**Trial status** 

Approved

Secondary Identifying Numbers	
Full name of issuing authority	Secondary identifying number
KSA	25325



Sources of Monetary or Material Support		
Name		
King faisal hospital		

Secondary Sponsors	
Name	
None	

Contac	Contact for Public/Scientific Queries					
Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public		Beirut	Iceland	0255.	@gmail	мон
Scientific		Beirut	Lebanon	56554	@yahoo	МОН

Centers/Hospitals Involved in the Study			
Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
AUB	RH	Oncologist	Approved
USJ	RH	Oncologist	NA

Ethics Review				
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center King faisal hospital	11/10/2018	RH	@gmail	565458

#### **Countries of Recruitment**

No Countries



Health Conditions or Problems Studied			
Condition	Code	Keyword	
heart failure	Heart failure (I50)	RF	

Interventions		
Intervention	Description	Keyword
pharmaceutical and behavioral	new medication with lifestyle changes	RH and forever

Primary Outcomes		
Name	Time Points	Measure
increast EF	in 6 months	EF

Key Secondary Outcomes		
Name	Time Points	Measure
I dont have	later	Ok



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	