Rasha 123

22/11/2024 03:50:49

Main Information

Primary registry identifying number
LBCTR2018090151

Protocol number
Rasha123

MOH registration number
20555/2018

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
15/09/2018

Primary sponsor
Rasha

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
22/04/2020

Date of registration in national regulatory agency
15/09/2018

Public title
Rasha 123

Acronym
RH

Scientific title
Rasha 123

Acronym
RH

Brief summary of the study: English
Great Job

Brief summary of the study: Arabic
السجل الوطني للابحاث السريرية
الاول من نوعه

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
Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum
18

Key inclusion and exclusion criteria: Age maximum
75

Key inclusion and exclusion criteria: Exclusion criteria
less than 18

Type of study
Observational

Type of intervention
Pharmaceutical

Type of intervention: Specify type
pharmaceutical with behavioral

Trial scope
Therapy

Trial scope: Specify scope
N/A

Study design: Allocation
Non-randomized controlled trial

Study design: Masking
N/A

Study design: Control
Uncontrolled

Study phase
1 to 2

Study design: Purpose
Treatment

Study design: Specify purpose
N/A

Study design: Assignment
Other

Study design: Specify assignment
single arm

IMP has market authorization
No

IMP has market authorization: Specify
USA

Name of IMP
In Love

Year of authorization
2014

Month of authorization
4

Type of IMP
Others

Pharmaceutical class
heart diseases

Therapeutic indication
to treat heart failure

Therapeutic benefit
increase ejection fraction

Study model
Case-Control

Study model: Explain model
OK

Study model: Specify model
N/A

Time perspective
Prospective

Time perspective: Explain time perspective

Time perspective: Specify perspective
N/A

OK

Target follow-up duration
30

Target follow-up duration: Unit
Months

Number of groups/cohorts
4

Biospecimen retention
Samples without DNA

Biospecimen description
DNA saliva samples

Target sample size
1000

Actual enrollment target size
1

Date of first enrollment: Type
Anticipated

Date of first enrollment: Date
20/10/2018

Date of study closure: Type
Anticipated

Date of study closure: Date
20/10/2020

Recruitment status
Complete

Recruitment status: Specify

Date of completion
24/04/2020

IPD sharing statement plan
No

IPD sharing statement description
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
NO one	55555

Sources of Monetary or Material Support

Name
King faisal hospital

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Rasha Hamra	Beirut	Iceland	0255.0000	rasha@gmail	MOH
Scientific	Marie Ok	Beirut	Lebanon	5655400000	marie@yahoo	MOH
Public	N N	Beirut	Belize	5555	r@yahoo	MOH

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
Makassed General Hospital	11/12/2019	RH	@yahoo	3336661

Countries of Recruitment

Name
Lebanon

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
New treatment	New	RH

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