



Rasha 123

22/11/2024 11:13:16

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

09/12/2019

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 للأبحاث السريرية
الأول 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

Interventional

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

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

Time perspective: Specify perspective

N/A



N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

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

Recruiting

Recruitment status: Specify

Date of completion

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 |

Sources of Monetary or Material Support

| Name |
|----------------------|
| King faisal hospital |

Secondary Sponsors

| Name |
|------|
| None |

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 | 565540000 0 | marie@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 |



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 |
|-------------|-------------|---------|
| increase 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