Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Assessment of left ventricular function by global longitudinal strain to detect subclinical Cardiomyopathy early after Busulfan therapy in patients undergoing bone marrow allogeneic transplantation

Protocol summary

Study aim
Assessment of left ventricular global longitudinal strain to detect subclinical Cardiomyopathy early after Busulfan therapy

Design
Single_arm clinical trial design of 14 patients,enroled between september 2017 and march 2018

Settings and conduct
Pateints undergoing Allogenic bone marrow transplant at Taleghani hospital assessed by a single operator ,by Simensce Prime [ACUSON SC2000] machine. Vector velocity imaging (VVI) method was utilized to calculate the global longitudinal strain component in 16 left ventricular segments and 3 persistent cardiac cycles. left ventricular Global Longitudinal Strain was mesured before and after Busulfan therapy.

Participants/Inclusion and exclusion criteria
Inclusion criteria :patients undergoing Allogenic bone marrow transplantation exclusion criteria :DM,HTN,Hyperlipidemia,Smoking,major valvular heart dis,CKD, initial EF less than 55%

Intervention groups
Echocardiograghy was done for Pateints undergoing bone marrow transplantation at the begining of the study.Busulfan dose was 0.8 mg/kg with intravenus infusion during two hours quarterly in four consecutive days; attaining 16 doses.After 7 days of Busulfan therapy patient was assessed again by the same operator.

Main outcome variables
Left ventricular Global longitudinal strain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191230045950N1**
Registration date: **2020-01-18, 1398/10/28**
Registration timing: **retrospective**

Last update: **2020-01-18, 1398/10/28**
Update count: **0**

Registration date
2020-01-18, 1398/10/28

Registrant information

Name
Seyede houra Yeganegi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-23, 1396/07/01

Expected recruitment end date
2018-03-20, 1396/12/29

Actual recruitment start date
2017-09-23, 1396/07/01

Actual recruitment end date
2018-03-11, 1396/12/20

Trial completion date
2018-03-20, 1396/12/29

Scientific title
Assessment of left ventricular function by global longitudinal strain to detect subclinical Cardiomyopathy early after Busulfan therapy in patients undergoing bone marrow allogeneic transplantation

Public title
Effect of Busulfan in left ventricular global lingitudinal strain
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing allogenic bone marrow transplantation
Exclusion criteria:
Diabetes melitus Hypertension Smoking Family history of Ischemic heart disease Major valvular heart disease Hyperlipidemia CKD Obesity Initial ejection fraction less than 55%
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **14**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti university of Medical Sciences
Street address
7th Floor, Bldg No.2 Shahid Beheshti University of Medical Sciences, Aarabi Ave, Daneshjoo Blvd, Velenjak, Tehran
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Province
Tehran
Postal code
19839-63113
Approval date
2017-12-17, 1396/09/26
Ethics committee reference number
Ir.sbmu.msp.rec.1396.664

Health conditions studied

1

Description of health condition studied
Cardiomyopathy
ICD-10 code
I42
ICD-10 code description
Cardiomyopathy

Primary outcomes

1

Description
Left ventricular function by Global longitudinal strain (GLS)
Timepoint
At the begining of the study and 7 days after Busulfan therapy
Method of measurement
Echocardiography

Secondary outcomes

1

Description
Left ventricular end diastolic volume
Timepoint
At the begining and 7 days after Busulfan therapy
Method of measurement
Echocardoography

2

Description
Left ventricular end systolic volume
Timepoint
At the begining and 7 days after Busulfan therapy
Method of measurement
Echocardiography

3

Description
Left ventricular ejection fraction
Timepoint
At the begining and 7 days after Busulfan therapy
Method of measurement
Echocardiograghy

Intervention groups

1

Description
Intervention group:Echocardiograghy was done for

Pateints undergoing bone marrow transplantation at the begining of the study and then 7 days after Busulfan therapy .Busulfan dose was 0.8 mg/kg with intravenus infusion during two hours quarterly in four consecutive days; attaining 16 doses.

Category
Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani hospital

Full name of responsible person
Seyede Houra yeganegi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammad Yousef Qoddossi

Position
Rezident

Latest degree
Specialist

Other areas of specialty/work
Cardiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available