Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of an arterial blood sampling device and its function in accelerating and facilitating blood sampling

Protocol summary

Study aim

Investigating and introducing a new inventive device for the first time in the world to improve errors and reduce damage during arterial blood sampling from patients.

Design

This randomized controlled clinical trial was performed on 100 patients hospitalized in Qaem and Imam Reza Hospitals of Mashhad, Iran in autumn and winter 2016. The first sampling was done by the conventional method (insulin syringe) and the second blood sample was taken by the inventive device. Sampling throughout the study was done by a single operator (ICU specialist).

Settings and conduct

The steps towards the inventive device performance are as follows: after placing the syringe in the device the operator holds the device with the prominent (right) hand on the skin and looks for the pulse with the left hand; then the needle tip is inserted into the skin and at this exact moment by pressing a key the device piston rises a few centimeters causing suction in the syringe.

Participants/Inclusion and exclusion criteria

Patients requiring at least two occasions to receive arterial blood samples from the radial artery a day were eligible to participate in the study if they were satisfied and patients with reduced consciousness (GCS<15), any type of arrhythmia, anatomic variations and low blood pressure which made it difficult to simply palpate the radial artery were excluded from the study.

Intervention groups

The first sampling was done by the conventional method (insulin syringe) and the second blood sample was taken by the inventive device.

Main outcome variables

The time required for blood sampling, the number of failed attempts and the number of times required for blind needle displacement, the incidence of adverse complications and also the patient and operator's satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181017041373N1**
Registration date: **2018-12-31, 1397/10/10**
Registration timing: **retrospective**

Last update: **2018-12-31, 1397/10/10**
Update count: **0**

Registration date

2018-12-31, 1397/10/10

Registrant information

Name

Farzaneh Farrokh Seir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 2256

Email address

farrokhsf941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-21, 1395/06/31

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

2016-10-02, 1395/07/11

Actual recruitment end date

2017-03-04, 1395/12/14

Trial completion date

2017-03-04, 1395/12/14

Scientific title

Evaluation of an arterial blood sampling device and its function in accelerating and facilitating blood sampling

Public title
Accelerating and facilitating blood sampling
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Patients need at least two times to receive an arterial blood sample from the radial artery a day Patient Satisfaction to Participate in the Study
Exclusion criteria:
Patients with reduced consciousness (GCS<15) Patients with any type of arrhythmia Anatomic variations Low blood pressure
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
More than 1 sample in each individual
Number of samples in each individual: **2**
The first sampling was done by the conventional method (insulin syringe) and the second blood sample was taken by the inventive device.
Actual sample size reached: **100**
More than 1 sample in each individual
Actual sample size in each individual: **2**
The first sampling was done by the conventional method (insulin syringe) and the second blood sample was taken by the inventive device.
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
In this study we aimed to investigate an inventive semi-automated blood sampling device for safe and facilitated arterial blood sampling. This is a small, pocked-sized and portable device which is made up of a syringe holder (without compromising its sterility), two compression keys for moving the piston and a battery.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences., Vakil Abad Blvd., Mashhad Town
City
Mashhad
Province
Razavi Khorasan
Postal code
345 - 91357
Approval date
2018-01-30, 1396/11/10
Ethics committee reference number
IR.MUMS.FM.REC.1396.668

Health conditions studied

1

Description of health condition studied
Arterial blood sampling
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The time required for blood sampling
Timepoint
After arterial blood sampling with the inventive device and conventional method (insulin syringe)
Method of measurement
Checklist provided by the researcher

2

Description
The number of failed attempts
Timepoint
After arterial blood sampling with the inventive device and conventional method (insulin syringe)
Method of measurement
Checklist provided by the researcher

3

Description
The number of times required for blind needle displacement
Timepoint
After arterial blood sampling with the inventive device and conventional method (insulin syringe)
Method of measurement
Checklist provided by the researcher

4

Description
The incidence of adverse complications
Timepoint
After arterial blood sampling with the inventive device and conventional method (insulin syringe)
Method of measurement
Checklist provided by the researcher

Secondary outcomes

1

Description
patient’s satisfaction
Timepoint
After arterial blood sampling with the inventive device and conventional method (insulin syringe)
Method of measurement
VAS Score

2

Description
operator’s satisfaction
Timepoint
After arterial blood sampling with the inventive device and conventional method (insulin syringe)
Method of measurement
VAS Score

Intervention groups

1

Description
Intervention group: Arterial sampling with the inventive device
Category
N/A

2

Description
Control group: Arterial sampling by the conventional method (insulin syringe)
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Qaem and Imam Reza Hospitals of Mashhad, Iran
Full name of responsible person
Farzaneh Farrokh Seir
Street address
Qaem and Imam Reza Hospitals., Taghi Abad Blvd., Mashhad Town
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3884 2256
Email
br8534@bmi.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Farzaneh Farrokh Seir
Street address
No. 17, Hashemieh 12 Blvd., Vakil Abad Blvd., Mashhad Town
City
Mashhad
Province
Razavi Khorasan
Postal code
9178646365
Phone
+98 51 3884 2256
Email
Farrokhsf941@mums.ac.ir
Grant name
Mashhad University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Farzaneh Farrokh Seir
Position
Resident

Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
No. 17, Hashemieh 12 Blvd., Vakil Abad Blvd., Mashhad Town
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3884 2256
Email
Farrokhsf941@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Farzaneh Farrokh Seir
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
No. 17, Hashemieh 12 Blvd., Vakil Abad Blvd., Mashhad Town
City
Mashhad
Province
Razavi Khorasan
Postal code
9178646365
Phone
+98 51 3884 2256
Email
Farrokhsf941@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Farzaneh Farrokh Seir
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
No. 17, Hashemieh 12 Blvd., Vakil Abad Blvd., Mashhad Town
City
Mashhad
Province
Razavi Khorasan
Postal code
9178646365
Phone
+98 51 3884 2256
Email
Farrokhsf941@mums.ac.ir

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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available