

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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

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Email

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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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

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